

Process evaluation of a pragmatic implementation trial to support self-management for the prevention and management of type 2 diabetes in Uganda, South Africa and Sweden in the SMART2D project

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To cite: van Olmen J, Absetz P, Mayega RW, *et al*. Process evaluation of a pragmatic implementation trial to support self-management for the prevention and management of type 2 diabetes in Uganda, South Africa and Sweden in the SMART2D project. *BMJ Open Diab Res Care* 2022;**10**:e002902. doi:10.1136/bmjdr-2022-002902

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjdr-2022-002902>).

Received 11 April 2022
Accepted 28 August 2022



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ABSTRACT

Introduction Type 2 diabetes (T2D) and its complications are increasing rapidly. Support for healthy lifestyle and self-management is paramount, but not adequately implemented in health systems. Process evaluations facilitate understanding why and how interventions work through analyzing the interaction between intervention theory, implementation and context. The Self-Management and Reciprocal Learning for Type 2 Diabetes project implemented and evaluated community-based interventions (peer support program; care companion; and link between facility care and community support) for persons at high risk of or having T2D in a rural community in Uganda, an urban township in South Africa, and socioeconomically disadvantaged urban communities in Sweden.

Research design and methods This paper reports implementation process outcomes across the three sites, guided by the Medical Research Council framework for complex intervention process evaluations. Data were collected through observations of peer support group meetings using a structured guide, and semistructured interviews with project managers, implementers, and participants.

Results The countries aligned implementation in accordance with the feasibility and relevance in the local context. In Uganda and Sweden, the implementation focused on peer support; in South Africa, it focused on the care companion part. The community–facility link received the least attention. Continuous capacity building received a lot of attention, but intervention reach, dose delivered, and fidelity varied substantially. Intervention-related and context-related barriers affected participation.

Conclusions Identification of the key uncertainties and conditions facilitates focus and efficient use of resources in process evaluations, and context relevant findings. The use of an overarching framework allows to collect cross-contextual evidence and flexibility in

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Process evaluations facilitate understanding why and how interventions work through analyzing the interaction between theory, implementation, and context. To efficiently use resources, process evaluations ideally focus on the most relevant uncertainties. This focus is often not made explicit.

WHAT THIS STUDY ADDS

⇒ This study adds new knowledge by identifying key uncertainties and context-specific questions for implementation in an overarching framework. Countries focused their in-depth implementation in accordance with feasibility and relevance in the local context.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our findings suggest the following key elements for designing an intervention: aspects of the implementing organization or structure, absorptive capacity, implementation feasibility (and fidelity), capacity and organizational context of the implementation team and/or recipients.

evaluation design to adapt to the complex nature of the intervention. When designing interventions, it is crucial to consider aspects of the implementing organization or structure, its absorptive capacity, and to thoroughly assess and discuss implementation feasibility, capacity and organizational context with the implementation team and recipients. These recommendations are important for implementation and scale-up of complex interventions.

Trial registration number ISRCTN11913581.

BACKGROUND

Non-communicable diseases (NCDs) such as type 2 diabetes (T2D) comprise the largest global burden of disease.¹ While efficacious interventions to prevent and control NCDs exist, contextualized large-scale implementation is lagging. Results of existing implementation studies vary² and negative findings seem to be linked to challenges in design and implementation.³ By analyzing the interaction between intervention theory, implementation and context, process evaluations facilitate in understanding why and how interventions work and how they can be strengthened for improved effectiveness, dissemination or scale-up to other population groups and settings.⁴

The 'Self-Management and Reciprocal learning for Type 2 Diabetes' (SMART2D) project implemented a self-management support intervention for T2D in three different settings: a rural community in Uganda (low-income country), a semiurban township in Cape Town, South Africa (middle-income country), and socioeconomically disadvantaged suburbs with a high proportion of immigrants in Stockholm, Sweden (high-income country). The aim of the project was to formulate and implement contextually appropriate self-management strategies for the prevention and control of T2D in each setting and to evaluate its outcomes.⁵ The SMART2D intervention, developed in a collaborative process with research teams and stakeholders in the participating countries,⁶ resulted in a complex intervention design with shared key functions but—for ensuring cultural fit in each setting—had contextualized content and delivery which operated on multiple levels.⁷ The intervention development took into account contextual weaknesses and strengths with regard to self-management support, identified through interviews with local stakeholders (local governments, community organizations, outreach workers, individuals with or at high risk of T2D, and healthcare providers).⁸

To efficiently use resources, process evaluations ideally focus on the most relevant uncertainties related to implementation in the context.⁹ This focus is often not made explicit by designers, implementers and researchers, which affects the quality and utility of such evaluations.¹⁰ The reciprocal learning approach in SMART2D¹¹ enabled the research team to identify uncertainties and operational research questions for each country context within an overarching evaluation framework. The Medical Research Council (MRC) guidance for process evaluations⁴ was used because it allows a comprehensive assessment of the implementation of complex interventions, taking into account delivery, participation and context. This paper presents a comprehensive analysis of the SMART2D implementation process and of the interaction with context and aims to contribute to an understanding of trial results.¹²

METHODS

Setting and context

The study was conducted in three settings, reflecting three contexts in which health systems are still struggling to diagnose and manage T2D effectively. In Uganda, a low-income country, the trial was conducted at nine primary healthcare facilities, located in the two rural districts of Iganga and Mayuge in the eastern part of the country. These are the primary healthcare facilities at which persons with diabetes first interface with the healthcare system for diabetes care. In South Africa, the trial was conducted at two community health centers in the Khayelitsha township in Cape Town in the Western Cape, which were purposively selected based on their demographic similarity, catchment areas and exclusion from other trials. In Sweden, the trial was conducted in two urban districts within Stockholm municipality representing socially disadvantaged suburbs. The interventions targeted participants recently diagnosed with or at increased risk of T2D. The study used a quasiexperimental design. Recruitment of potential participants was conducted within the catchment areas, and at the health facilities as described below.

Aim and design of the SMART2D intervention

The intervention package consisted of facility and community strategies.^{7 13} The study consisted of an adaptive implementation trial with a quasiexperimental design, conducted in a sample of patients with T2D, and a sample of individuals at high risk of T2D. The trial arms included the facility plus community care (integrated care) arm, and the facility-only care (facility care) arm. The main aim of the facility strategies was to standardize a minimum level of care across the two study arms. In Uganda, where primary care processes for T2D are not regularly fully provided, a third arm, the usual care arm, was added to serve as control arm. Participants were eligible if they fulfilled the following criteria: aged between 30 and 75 years, had resided in their respective communities for at least 6 months, no plans of outmigrating over the next 12 months; able to provide written informed consent; allow home visits and follow-up contacts; and a diagnosis of T2D of no longer than 12 months, or a diagnosis of pre-diabetes. Implementation of the intervention was conducted during 9 months in Uganda and South Africa, and 13 weeks in Sweden.

This paper focuses on the community strategies of the integrated care arm that are deemed most important for transfer and scale-up, evaluated through an adaptive implementation trial in Uganda and South Africa and a feasibility trial in Sweden: (a) community mobilization; (b) peer support program; (c) care companion (CC); and (d) community extension, linking the community and facility.⁷ Community mobilization included messages on lifestyle and T2D for community members/key stakeholders, information, and recruitment sessions. The peer support program was organized in facilitator-led meetings with a set structure and topics and introduction to T2D

risk factors and complications; healthy eating; physical activity; alcohol and smoking; self-care and medications; and community walks. Facilitators received training. The CC intervention was implemented by asking all patients to identify a significant other who could support him/her in self-management and providing emotional, practical, and ongoing support. The participant and CC received explanation and a brochure. The community extension was implemented through community link teams consisting, ideally, of representatives of patients and CC, primary care and local administration and/or non-governmental organizations (NGOs) with the task to advocate for and support healthy lifestyles in the community, to support implementation of community strategies; and to form a linkage between the facilities, local administrations and the community. The follow-up duration of participants was 12 months in Uganda, 9 months in South Africa and 3 months in Sweden.⁵ Deviation from the protocol in Sweden was related to major changes in intervention delivery after a pilot study had shown poor acceptability of the group-based peer support program, resulting in an individual telephone-facilitated health coaching program.⁷

The assumptions underlying the intervention and mechanisms of impact originated in the transdisciplinary conceptual framework developed for SMART2D based on the self-determination theory (SDT).⁸ Community mobilization (was assumed to) increase knowledge and awareness among potential participants, a prerequisite for perceived self-efficacy. The peer support facilitators operating face-to-face peer groups (Uganda and South Africa) or telehealth coaching sessions (Sweden) were trained to use person-centered techniques from motivational behavioral coaching to foster participants' need for autonomy, relatedness, and competence in making lifestyle changes. There were six T2D-specific self-management topics to guide the peer support sessions, but the number of sessions was higher to allow people flexible attendance based on their availability. Based on the SDT framework, satisfaction of these needs was hypothesized to lead to increased autonomous motivation, in turn resulting in more sustained behavior change.¹⁴ The CC intervention, delivered by a significant other or someone in their social network, was assumed to contribute to perceived relatedness through emotional, practical, and ongoing support of study participants. The community-facility link was hypothesized to ensure the flow of information, feedback, and support between community and facility. Implementation of the community extension was achieved through study participant peer group leaders and nurses in Uganda, expanding the role of community health workers (CHWs) in South Africa, and inspiration meetings bringing together participants and community and facility actors in Sweden.

The SMART2D intervention was a complex intervention because of its multiple interacting components and the narrow interaction between local context and implementation.¹⁵ The research team and local

implementation teams were in frequent contact for the (adaptation of) intervention delivery, by addressing organizational and logistical challenges to ensure adequate research design and delivery of active ingredients of the intervention. This also meant coping with changes in local health service organization or policies, such as the reorganization of health districts or transfer of staff. These changes meant continuous reassessment of barriers and uncertainties, which asked for a flexible evaluation framework allowing researchers to go back and forth in the sequence of data collection and analysis and to have repetitive interactions with implementers and local stakeholders. These dynamics resulted in the joint determination of targets for process and outcomes of the implementation strategy, established in a joint implementation evaluation framework.

Evaluation framework and measures of the implementation strategy

Evaluation was based on the MRC guidance⁴ and the taxonomy of implementation outcomes,¹⁶ allowing to structure the evaluation into three parts: (1) components of the intervention and interaction with context; (2) implementation; and (3) mechanism of impact (participant level) (figure 1). Evaluation components for the implementation outcomes included: capacity building (training and supervision); reach (proportion of the target population reached by the intervention); dose delivered (quantity of the intervention (measurable only for component b), the target being participants having received at least one-third of all sessions which would allow them to have covered the six topics in the peer support program); fidelity (implementation according to protocol); and adaptations to the implementation protocol. The evaluation components for mechanisms of impact were: participation of study subjects in activities; mediators defined as the interaction of participants with the intervention; and barriers and facilitators. Participation and mediators were not relevant for strategy d, since this was not targeting study participants. Since component a was primarily meant to boost participation to the core components b–d, this component was only assessed for reach and participation. The context factors were relevant to all elements and are therefore placed on top in the figure. They included the health facility which participants attended and influences from the wider environment. Measures used for the evaluation of these elements are described in table 1.

Measures, data collection and analyses

Measures were developed for the evaluation of the implementation and the mechanisms of impact for each of the four intervention components. Table 1 provides the adaptation of the MRC taxonomy to the intervention components and the context, and measures and sources of data collection. The latter included structured and informal observations of field visits by project management staff, interviews with

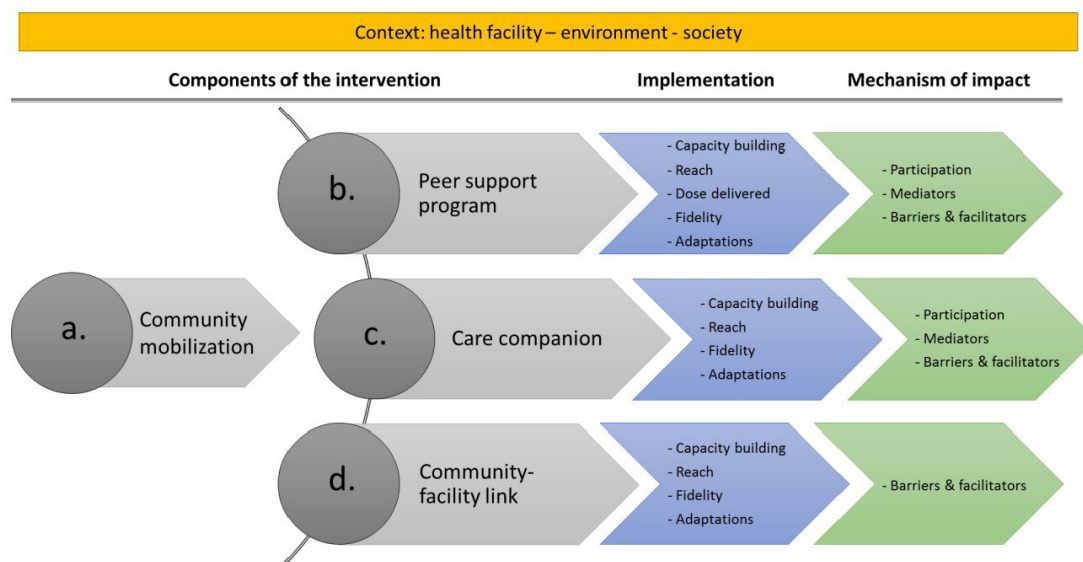


Figure 1 Self-Management and Reciprocal Learning for Type 2 Diabetes (SMART2D) process evaluation framework.

implementers and participants, project documents including participant attendance lists, country reports (which in Sweden were based on a REDCap continuous intervention tracking tool) and monthly SMART2D consortium meetings. Structured process evaluation tools included interaction checklists contextualized into a peer group checklist (online supplemental web annex 1a, Uganda); a quality assurance checklist (online supplemental web annex 1b, South Africa); a quality assurance/interaction tool (online supplemental web annex 1c, Sweden); and a CC checklist (online supplemental web annex 2). The analysis is based on the findings from both the structured tools and the reports. We assured internal validity of the analysis through the following checks and balance: use of different data sources, triangulation of these different sources, phased analysis with country-specific and non-country-specific researchers with feedback loops between both teams for discussion and multiple observations and interviews until data saturation.

During the development and early implementation stages, research team observations led to the identification of context-specific questions for implementation. Countries developed additional process evaluation measures to answer these context-specific questions: Uganda evaluated the facility intervention component (facility checklist, online supplemental web annex 3) and compiled an overall process evaluation report¹⁷; South Africa assessed the capacity building of the implementing organization; and Sweden assessed the recruitment, reach and acceptability of the intervention and the interaction between facilitators and participants.¹⁸ These data were reported separately but also provided more in-depth understanding of the cross-country evaluation. Each of the three country implementation managers (LT, FK, MH) filled in the cross-country data collection table using these primary

data. This was further discussed and clarified within country teams and in two cross-country meetings.

RESULTS

Table 2 gives an overview of the process evaluation results for context, community mobilization and the three intervention components as implemented at the three sites.

Context and the influence on the intervention

The wider societal and policy context influenced the implementation in all three countries. In South Africa, the national policy on CHW activities changed during the project, which led to a change in geographical catchment areas and incentive systems. The facility context provided routine care and prevention in the community intervention. In South Africa and Sweden, facility staff were informed about the community intervention, but T2D care went on as usual. In Uganda, to guarantee at least the minimum level of quality care for all participants, facility care was upgraded with participants in all study arms receiving adequate medication and staff in the active intervention arms receiving training in T2D health education.

Environmental factors influenced the different options for intervention delivery. The choice to involve an existing service organization in South Africa was rooted in the health system tradition of using CHWs. This facilitated the delivery process because it engaged an existing cadre of local health workers that was familiar to participants. CHWs took up a modified role as CC and focused more on behavior change support. The organizational context, including weak management and high staff turnover, however, affected the perceived support of CHWs. The physical environment in Uganda was rural, and peer support was organized around parish communities, where existing social capital leveraged group

Table 1 Data collection table (horizontal sequence figure 1 transposed to a vertical sequence)

MRC concepts		Adaptation to SMART2D intervention	Operationalization into topics and measures	Source of data and data collection tools
Context		Health facility Environment	Routine care; interaction with research project Presence of health community organizations; community ties; physical environment	Project manager
Community mobilization				
Implementation	R	Reach	Settings in which recruitment was done	Consortium reports
			Duration of recruitment	
	A	Adaptations	Problems and adaptations	
	P	Participation	Number of people screened Number of people enrolled Problems experienced by potential participants	Site reports; monthly consortium meetings
Peer support program				
Implementation	C	Capacity building	Number of peer leaders/facilitators trained Number of initial trainings Number of refresher trainings Other supervision/monitoring activities	Project manager, consortium reports
	R	% target audience in contact with interventions	Number of invitations sent to participate in peer support sessions Number of peer groups established: group size (median, range)	Project manager, consortium reports
	D	Number of sessions delivered	Number of meetings/group: median, range	
	F	Fidelity with protocol	Number of groups covering all manual topics Topics not (or hardly) covered	
Mechanisms of impact/participation			Checklist/facilitator: 2Q (U)/7Q (SA)/10Q (SW)	Online supplemental web annex 1a–c
	A	Adaptations	Problems and adaptations	Facilitators
	P	Responses to intervention	Number of people who attended at least 1 session Number of individual contacts/participant Number of people having attended one-third of total sessions	Peer support reports
	M	Interaction with facilitator	Checklist/participation: 2Q (U)/3Q (SA)/4Q (SW)	Online supplemental web annex 1a–c

Continued

Table 1 Continued

MRC concepts		Adaptation to SMART2D intervention	Operationalization into topics and measures	Source of data and data collection tools
b	B/F	Barriers/facilitators	Problems experienced by participants	Participant interviews and project managers
	Care companion (CC)			
	C	Capacity building	Development and distribution of CC guide	Online supplemental web annex 2
	R	% target audience reached by the intervention	Number of participants being offered the option of CC	Project manager, consortium reports
	F	Fidelity with CC guidelines	Explanation of 6 CC tasks to CC	
	A	Adaptations	Systematic invitation to clinic visits and peer support	
Mechanisms of impact/participation				
c	P	Identification of CC	Number of people having a CC/engaging with a CC	Peer support reports, care companion checklist (SA)
	M	Engagement of CC in the 6 tasks	Reminding/participation in clinic visits and/or peer support program (tasks 1, 4)	
			Reminders to participants on medication and monitoring (tasks 2, 3)	Interviews CC, participants, and program managers
			Supporting physical activity and healthy diet (tasks 5, 6)	
	B/F		Problems experienced by peers	
	Community-facility link			
Implementation	C	Capacity building: training	Explanation/discussion about expectations	Project manager, consortium reports
	D	Implementation: dose delivered	No community actors in contact with facility actors	
	F		Introduction between actors	
	Mechanisms of impact/participation			
	B/F	Barriers/facilitators		
	A, adaptation; C, capacity building; D, dose delivered; F, fidelity; M, mediator; P, participation; Q, question; R, reach. MRC, Medical Research Council; SA, South Africa; SMART2D, Self-Management and Reciprocal Learning for Type 2 Diabetes; SW, Sweden; U, Uganda.			

Table 2 Results of process evaluation — part II

MRC concept	Measures	Uganda	South Africa	Sweden
Context				
	Health facility: routine care; interaction with research project	Routine care was strengthened; strong interaction with research project strengthened through pre-existing collaboration	Routine care as usual; little interaction with research project but more interest from staff in the control site	Routine care as usual; interaction with research team interrupted due to change of site
	Environment: presence of health community organizations; community ties; physical environment	No health community organizations; strong community ties; rural area — long travel distances	Presence of NGO with CHW; frequent migration hinders strong community ties; urban-disadvantaged neighborhood, safety concerns	Diabetes NGO not reaching target population; community ties weak, social gatherings religiously/socially inspired; urban-disadvantaged areas
	Organizational context: daily management	Peer groups, support by research field manager	CHW non-governmental organization	SMART2D research team
a Community mobilization and recruitment				
Implementation				
R	Recruitment settings	Community house-to-house visits	Facility chronic care clinics	Community public spaces; facility registers
	Duration (months)	11	18	18
A	Problems and adaptations	Large team of field assistants; need for strict quality control screening	Change of site delayed familiarization; university turmoil delayed teamwork; community sensitization event	Change of site; two-step screening led to loss in recruitment, adaptation to one step and inclusion changed to high risk
Participation				
P	Total number of people screened	28 976	2150	1965
	Number of people enrolled in community intervention	268	285	131
	Problems experienced by potential participants	Enrollment at facility-implied travel and waiting	High mobility linked to circular migration decreased long-term participation	Language barriers
b Peer support program				
Implementation				
C	Number of peer leaders/facilitators trained	19	10	6
	Number of initial+refresher trainings	4+2	3+2	9
	Other supervision/monitoring support activities	2 supervision visits/group	Weekly common mock sessions and quality assurance visit	4 facilitator-mentor meetings

Continued

Table 2 Continued

MRC concept	Measures	Uganda	South Africa	Sweden
R	Number of invitations to participants for peer support sessions	1900	375	1281
	Number of peer groups established and group size (median, range)	19 groups: size 10 (4–27)	3 groups: size 15 (10–20)	72 peer-coach dyads
D	Number of meetings/group: median (range)	10 (NA)	2 (1–2)	3.5 (1–9)
F	Number of groups covering all manual topics	17	None	49
	Topics not/hardly covered	Alcohol and drug risks; community walk	Community walk; goal setting	Care companion activities
	Quality of facilitation	Overall score 7 out of 10	Median score 4 out of 5 (IQR 4–5) on leadership/content	Median score 81 out of 100 (IQR 76–94) on delivery; 75 (70–78) on interest
A	Problems	Manual too difficult; language not adapted	Management problems at implementing organization: slow skill building, manual not followed, poor record keeping, locations small	Participants hard to reach, several phone calls needed
	Adaptations	Retranslated, mock sessions	More time, mock sessions; experienced peer facilitators to support testing opportunity increased attendance	Individual coaching sessions
Mechanisms of impact/participation				
P	Number of people who attended at least 1 session	100%	61/285 ~21%	72/131 ~55%
	Number of people who attended one-third of total sessions	76/268 ~28%	53/285 ~19%	49/131 ~37%
M	Interaction with facilitator	Good: average score 7 out of 10	Median score 4 out of 5 (IQR 4–5) on participation	Good: median 75 out of 100 (IQR 69–81) on engagement
B/F	Problems experienced by participants	Timing sessions interfere with work, especially in agricultural season	Timing, safety, weather, migration/informal settling, change of cellphone, other duties	No time; language; variability in preknowledge
c	Care companion (CC)			
Implementation				
C	CC guide	Brochure	Information to CHW, not to patients	
			Oral information and brochure	

Continued

Table 2 Continued

MRC concept	Measures	Uganda	South Africa	Sweden
R	Number of people being offered the option of CC	268/268 ~100%	208/285 ~73%	72/131 ~55%
F	Explanation of 6 CC tasks to CC	By nurse at health center	Partly	By facilitator and at sessions
	Systematic invitation to clinic visits and peer support	Yes	Yes	Yes
A	Problems and adaptations	Failure to identify CC	Patients did not identify a peer; CHW became CC; little knowledge transfer	Patients did not want/peers did not want
		Encouragement	Retrain and prep sessions on expectations	Pairing participants; multiple peers
Mechanisms of change/participation				
P	Number of people having a CC	268/268 ~100% (on paper)	CC performing at least one-third of agreed (home) visits: 185/285 ~65%	43/131 ~33%
M	Reminding/participation in clinic visits and/or peer support program	CC attendance of community activities (42/268 ~16%)	Yes	Some joint activities
	Reminders to participants on medication and monitoring	Active CC (roughly 50%) provided medication reminders	Yes	Not done
	Supporting physical activity and healthy diet	Active CC (roughly 50%) reminders, sometimes support in cooking	Focus on setting goals	Limited attempts for joint activities
B/F	Problems by peers	Many elderly, living alone		People did not want/unable
d Community-facility link				
Implementation				
C	Explanation expectations	Yes	No	Training meetings in behavior coaching
D	Number of community actors in contact with facility actors	17: materials and feedback reciprocal	Informal: not linked to community intervention	2 meetings for all actors: facilitators, care workers, patients and experts
F	Introduction between actors	Yes	Not in a structured way	Yes
Mechanisms of impact/participation				
B/F	Barriers/facilitators		CHWs contact health workers not structural, relationship perceived as unequal by CHW	Low interest in the other side of the link, little time investment done
Denominator is number of people enrolled in community intervention. A, adaptation; C, capacity building; D, dose delivered; F, fidelity; M, mediator; P, participation; R, reach. CHW, community health worker; MRC, Medical Research Council; NA, not applicable; NGO, non-governmental organization; SMART2D, Self-Management and Reciprocal Learning for Type 2 Diabetes.				

development. The urban environments in South Africa and Stockholm proved to be contexts with less social cohesion or community ties. In South Africa, safety issues threatened intervention and participation: the office was burgled and both facilitators and participants faced robbery attempts on their way to meetings. In Sweden, participants were often constrained by economic hardship, language barriers and feelings of isolation, but the peer support intervention provided an opportunity to build valued relationships of trust. The research partner was also a trusted partner in all three country contexts.

Community mobilization

Mobilization strategies were primarily used to boost participant recruitment and included information campaigns through brochures, posters and local information channels covering issues about lifestyle, T2D, screening and healthcare services in the study area. Uganda focused on the community for mobilization, South Africa and Sweden also included activities and screening in the health facilities¹⁹ and lasted 11 months in Uganda and 18 months each in Sweden and South Africa. In Uganda, 28 976 households were visited for screening and 268 participants were enrolled in the community intervention arm (142 people with T2D and 126 people at high risk). In South Africa, 2150 people were screened as eligible and 285 participants were enrolled in the community intervention arm (140 T2D and 145 persons at risk of T2D). In Sweden, 1965 people were screened in the communities²⁰ and patients with T2D were recruited through registers at primary healthcare centers, enrolling 131 participants in the community intervention arm (51 with T2D and 80 at high risk). A common recruitment barrier was the no-show of potential participants for the fasting plasma glucose test after the first contact was made, especially for the community-based screening. In Uganda, the need to do a facility-based third test meant travel and waiting time for participants. In South Africa, the high mobility, frequent change of cellphone numbers and lack of perceived interest led to high attrition rates after the recruitment phase. Similarly, in Sweden, it proved challenging to commit participants to a research project over an extended period of time.

Peer support program

Implementation

In Uganda, peer group leaders were fellow patients identified from each group and trained as facilitators; hence, the number of facilitators was larger (19) than in the other two settings. In South Africa, the project partnered with a local NGO which conducted community health work and trained 10 CHWs as facilitators. In Sweden, six research assistants were trained as peer supporters/facilitators. Although the profile of facilitators was different in each country, similar needs were observed to ascertain fidelity: refresher trainings and mock sessions were organized to build capacity in motivational coaching and group facilitation. This increased clarity about role

expectations: 'Being a facilitator means, letting them talk. Now we know' (South Africa). In each country, facilitators strived to maintain contact with participants throughout the intervention. This was time intensive at time: 'Frustrating is that they now come in the weekend to ask for testing. You have to go—if you refuse, you break the trust. It is not a bad thing, because you have a relationship, you care' (South Africa). In Uganda, 19 peer groups were established and a median of 10 sessions were organized per peer group. Study participant groups were able to self-organize and adapt place and time to their needs. In South Africa, only three groups were established covering roughly 75 participants with a varying composition including non-study participants. The groups convened once or twice, organized and facilitated by the NGO leading the intervention. Facilitators in Sweden established 72 peer-facilitator dyads with a median of 3.5 sessions per participant, and an average of six phone call attempts before contact could be established. Intervention fidelity in Uganda was assessed through a combined fidelity/participation score (averaging 7 out of 10).¹⁷ In South Africa, only five sessions were scored for fidelity, with initial sessions scoring very low, but later sessions improving. Qualitative reports and observations revealed that the group discussions focused on acute concerns of participants, rather than following the structure of the manual. Individual goal setting was difficult but the recapturing at follow-up meetings facilitated new reflection. Sweden showed a high intervention fidelity, measured on two axes.

Mechanism of impact

Participants were considered to have received a minimum dose of intervention if they attended one-third of the sessions, which included 76 people (28%) in Uganda, 53 people (19%) in South Africa and 49 (28%) in Sweden. Consistent attendance was a major challenge in all countries due to the timing of sessions, perceived lack of time, and other barriers such as transport costs, weather, and migration. The possibility of glucose testing was an additional incentive for attending in South Africa and Uganda. In Uganda, participants appreciated sharing experiences, the peer motivation and follow-up of medical appointments. 'Motivational coaching is the process where we share experiences with each other'. 'Because of the discussions, some patients now enjoy digging which they take as an exercise rather than a punishment' (two patients, Uganda). Diet was the topic most favored in discussions. Perceived need for participation was affected by variation in pre-existing knowledge, background, and stage of disease, with the highest interest among people diagnosed with T2D. Group leadership was a crucial variable explaining variability among peer group attendance.¹⁷ In South Africa, participants engaged in group discussions, especially in the smaller groups. In Sweden, peer support was highly valued by those who completed the program, especially the social support emerging from the connection built.

'Social support is an important thing, different from self-efficacy support' (Sweden). However, as a side effect of the strong rapport, participants did not seem to perceive active CCs as an important component. Some facilitators were active in suggesting goals, but others also encouraged participants to find a CC and set up goals together.

Care companion Implementation

The CC component was introduced to participants at facility level in Uganda and by telephone-facilitated health coaching facilitators in Sweden. Most participants identified a spouse, other household members, or a close neighbor as their CC, as they experienced difficulties to identify other persons or were hesitant to ask. In Sweden, the intervention team adapted by expanding options, for instance, pairing participants during facility–community link meetings and suggesting multiple CCs for different activities. In South Africa, early recognition of barriers for identifying a CC in a population with a lot of circular migration²¹ led to an adapted model of CHWs acting as CC.

Mechanism of impact

In Uganda, 269 participants (100%) reported to have a CC, in South Africa 208 out of 285 (73%), and in Sweden 61%. Active involvement of CCs was hindered by time and resource constraints and a lack of perceived relevance, especially when patients were considered stable, as shown in the following quote from a CC: 'The battle is not for care companions; it is for the people (who are) affected' (Uganda).¹⁷ In Sweden, some participants related to the individualistic culture of the context, which made it difficult to seek support. Upon encouragement by the peer support facilitator, some did find a CC. A joint attendance at the inspiration meetings (community extension) could be a joint activity or sometimes establish a CC relationship. CCs were positive about the new knowledge gained at these meetings. However, the participants did not report on specific roles or support of their CC to achieve their self-management goals. In Uganda, patients reported that the key roles of CCs were to support them in doing physical activity, eating healthy and taking their medication. In South Africa, interviews with CHWs revealed that they felt insufficiently prepared for their new role as CC. While they received immediate feedback in the training sessions for the (group-based) peer support sessions, they lacked training and on-the-job supervision on how to apply behavior coaching during the household visits. They perceived the new roles to be part of the research project; not a part of their formal job description. They also reported that their CHW uniforms contributed to prefixed expectations from people.

Community extension Implementation

This aimed at strengthening the link between the community-based intervention and health facility actors.

In Uganda and Sweden, introduction meetings between peer support program facilitators and healthcare staff were organized. In Uganda, regular contact was established through exchange of self-management material and sharing information around defaulters. Community actors reported a general lack of time and interest from healthcare staff towards their activities: 'Communication between us and the nurse is very bad' (South Africa). Nevertheless, they experienced synergy from facility activities as health education given by nurses encouraged attendance to the peer support program and reinforced peer program information. In South Africa, the link between facility and community was presumed pre-established through CHWs who delivered medication during home visits, and no additional actions were organized. The project team observed that the hierarchical facility context and healthcare worker attitudes towards the tasks of CHWs were negative, which hindered a cross-fertilization between community and facility support. In Sweden, four neighborhood meetings were organized for participants and CCs, joined by healthcare givers, T2D experts, and community actors, focusing on information exchange and establishing relationships. These were well received.

DISCUSSION

The analysis of the implementation process of a community T2D prevention and self-management support intervention revealed how the context shaped implementation delivery and participation in three different contexts. Three key findings on implementation emerged from this study. First, comprehensive in-depth implementation of all the intervention elements as planned did not occur. Countries instead focused their in-depth implementation on specific elements based on context-related conditions and deemed relevance. Second, continuous capacity building received a lot of attention across settings, but intervention reach, dose delivered and fidelity varied substantially. Third, participation in the intervention was lower than expected due to intervention-related and context-related barriers. Our findings provide an explanation of the effect of the community intervention on primary outcomes, which were improved glucose control and lower incidence of T2D, in Uganda and South Africa, respectively.¹² In Sweden, the focus was on the feasibility of the intervention, hence, the short implementation period of 3 months was insufficient to evaluate effectiveness.

The three countries had a comprehensive intervention program but focused their in-depth implementation in accordance with the feasibility and relevance in the context. In Uganda and Sweden, the implementation focused on the peer support intervention whereas in South Africa, it centered around the CC part. The outcome assessment data did not allow comparison in terms of effectiveness of these different components. The community–facility link received the least attention

overall in the implementation. The lack of perceived relevance among professional healthcare workers for this part, especially in South Africa, but to a lesser extent also in Uganda, was found to be a barrier, as was reported in similar studies.²² A stronger focus on this element could in theory have contributed to more capacity building for the community intervention, and certainly have created a more supportive facility context. Qualitative reports on the contact between peer leaders and facility staff and the modestly positive effects of the intervention in Uganda show the potential for this.

The context analysis illustrates how context shapes the possibilities of the intervention, and at the same time affects the mechanism of impact. Intervention implementation depended on available resources: in Uganda, the absence of existing community organizations resulted in the establishment of new structures supported by a field coordinator, while in South Africa, the collaboration with an already existing NGO seemed logical. However, the weak managerial context and predefined job descriptions of CHWs in the latter appeared to be a constraint. Other studies also point to the importance of organizational context and role definition in capacity building.²³ Embedding the intervention in a research project across settings, however, provided the implementation with credibility towards participants for the duration of the project.

The facility context, in which participants received their healthcare, was also assessed. The strengthening of facility-based care in Uganda, especially improved access to medication, changed the context for all participants (intervention and control) and contributed to participant retention and support for the community intervention. The community extension component could potentially have changed the facility context in other countries but this was less visible.

In Uganda and South Africa, the focus was on capacity development of facilitators, which, however, did not increase capacity to the expected levels. The performance of peer support facilitators was variable. In South Africa, project managers reported problems in implementation fidelity, which they linked to a lack of formative work on how CHWs could integrate their newly acquired knowledge on motivational coaching into daily practice. This highlights the importance of absorptive capacity and supportive environment to acquire and operationalize new skills.²⁴

Monitoring participation reliably was challenging in Uganda and South Africa but seemed relatively low in terms of group attendance and CC support. In Sweden, monitoring of this aspect could more easily be integrated into the largely research team-led activities, revealing that, first of all, mobilization of participants was more difficult than expected. Many potential participants faced a language barrier to understand the Swedish-informed consent procedure and, despite the eagerness to be tested, seemed hesitant to join the intervention. Our formative research

in this setting suggested that potential participants had mixed perceptions about the potential supportive role of family and friends in the private matter of health and about weak relationships in the community.⁸ Evidence from other studies also points to barriers among vulnerable populations, including distrust of research, lack of confidentiality, fear of safety, schedule conflicts, poor access to medical care, lack of knowledge, language and cultural differences.²⁵ Ongoing analysis shows that participants, once having started the intervention, received it very well and quickly built a good rapport with their facilitator.²⁶ For the peer support intervention, all countries reported that engagement interest leveled off after several sessions. Ongoing analysis of the impact of the intervention on motivational mediators will provide more insights on how well the intervention has induced mechanisms of change at the individual level.

Our findings compare with other studies that report on barriers towards implementation of self-management support interventions involving peer groups and CCs.^{27–29} Reported success factors of peer support are the right timing of support visits to coincide with patient needs, and the embedding in a broad network of other support services.³⁰ In SMART2D, we presumed the highest need to be present after a new diagnosis for people with T2D, but this was not examined in the situational analysis. The community–facility link could have strengthened this embedding of the intervention, which however proved to be difficult in our study. A recent review of implementation research in low and middle-income countries (LMICs) questions the relevance and feasibility of interventions that address individual patient needs and behavior change in health systems that are not patient centered.³¹ Many included studies reported that organizational cultural or language barriers regarding practice norms made this construct particularly difficult to apply in an LMIC setting. The mediating effect of the context on individual motivation at baseline was described elsewhere.^{32–33} Further analysis will show whether the SMART2D intervention was able to affect individual-level mediators of change.

Strengths of this evaluation are its theoretical basis; frequent interactions between teams of different settings allowing for deep understanding; and a focus on context-specific evaluation needs. We also adapted qualitative methods customized to the context, focusing on the matter of uncertainty in each context. Implementation in this pragmatic trial was a non-linear process and the process evaluation sheds light on why some aspects of the intervention did not work as expected. The limitations of this study pertain to the completeness and the variation in the quality of data collected. Like in many research projects, resources were limited and focused on implementation and not on documentation. This process evaluation focused mostly on the element of the peer support program,

limiting its scope. This reduced the potential of the process evaluation to assess, for instance, the fidelity of the CC intervention, and the mechanism of impact. The training and quality control of data collectors were limited, especially about the rating of the scales. This is clearly seen in the variability of the interactivity scores of the peer group component. The qualitative information provided by the data collectors in meetings with the evaluation team provided more detail and background about the process and interpretation.

The reports of implementing agents (peers, CHWs) were not always of consistent quality, which affected the comprehensiveness of the evaluation results. The frequent interactions in the consortium allowed for formal and informal communications which enriched the cross-contextual understanding and the understanding of the findings in the process evaluation.

CONCLUSIONS

Process evaluations are crucial to implementation research. The explicit focus of this process evaluation increased the relevance and utility for the three contexts. Identification of the key uncertainties and conditions facilitates focus, efficient use of resources and context-relevant findings. This asks for a flexible design so that additional research questions and tools can be developed to respond to observations and to newly evolving routes during the implementation phase. The overarching framework was instrumental to collect evidence across contexts and to structure reciprocal learning. The frequent interactions including informal exchanges were a rich source of data for the process evaluation and contributed to the deeper understanding of implementation. The findings of this process evaluation point to recommendations for implementation and scale-up. When designing an intervention, it is crucial to consider aspects of the implementing organization or structure, absorptive capacity, and to thoroughly assess and discuss implementation feasibility, capacity and organizational context with the implementation team and recipients.

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Acknowledgements We are grateful to the institutional support of the country site institutions to the SMART2D consortium. The SMART2D consortium included the following six partner institutions: Makerere University, School of Public Health, Uganda; the University of the Western Cape, School of Public Health, South Africa; Karolinska Institutet and Uppsala University, Sweden; Institute of Tropical Medicine, Belgium; and Collaborative Care Systems Finland. We acknowledge the contribution of the other SMART2D consortium members: David Sanders deceased, Barbara Kirunda, Anthony Muyingo, Ronald Kusolo, and Edward Ikona. We also acknowledge the study participants for volunteering to participate in the trial, the contribution of the participating health centers and their staff in Uganda and South Africa including The Caring Network Community Health Workers and Management, Diabetes SA, Katherine Murphy and Buyelwa Majikela-Dlangamanga from the Chronic Disease Initiative for Africa, Tshilidzi Manuga and Sunday Onagbiye and the entire field worker team from South Africa.

Contributors JvO took the lead in the design, analysis and drafting of the paper. PA, DG, JvO, MD and TP conceived and designed the trial. JdM developed the theoretical framework. DG, PD, PA, JvO, KSA, LT, HMA, TP, FK, GN, MH, RWM and the SMART2D Group implemented the trial. C-GÖ and GT supported the implementation and dissemination in Sweden and Uganda. JvO is responsible for the overall content as the guarantor. All authors participated in writing, and read and approved the final manuscript.

Funding This study was part of the SMART2D project funded by the European Commission's Horizon 2020 Health Coordination Activities (grant agreement number: 643692) under call 'HCO-05-2014: Global Alliance for Chronic Diseases: prevention and treatment of type 2 diabetes'. The Uganda site was cofunded by the Sweden International Development Cooperation Agency (SIDA) capacity-building grant to Makerere University 2015–2010 (project number: HS 343).

Disclaimer The contents of this article are solely the responsibility of the authors and do not reflect the views of the funders of the SMART2D project.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the ethics committee in each of the respective countries, including the Higher Degrees, Research and Ethics Committee of Makerere University School of Public Health (reference number: 426) and the Uganda National Council for Science and Technology (ref: HDREC-HS 2118) in Uganda; the Office of the Dean, Department of Research Development of the University of the Western Cape, South Africa (ref: BM/17/1/36); the Regional Ethics Review Board in Stockholm, Sweden (ref: 2015/712-31/1), and the Institute of Tropical Medicine Institutional Review Board, Belgium (ref: 993/14). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data are available upon request.

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WebAnnexes**Webannex 1a) Peer group checklist (Uganda)**

Country			
Group ID			
Date of meeting			
Meeting number / All meetings	____ / ____		
Attendance:			
Number of participants allocated to group	_____		
Number of participants present	_____		
Number of Care companions present	_____		
Duration:			
Starting time	_____		
Ending time	_____		
Content:			
Meeting topic:	_____		
Content covered:	<input type="checkbox"/> Fully	<input type="checkbox"/> Partly	<input type="checkbox"/> Not at all
Process:			
Utilization of participatory activities*	<input type="checkbox"/> All the time	<input type="checkbox"/> Sometimes	<input type="checkbox"/> Not at all
Identification of strengths**	<input type="checkbox"/> For every pt	<input type="checkbox"/> For some pts	<input type="checkbox"/> Not at all
Goal setting for individuals	<input type="checkbox"/> For every pt	<input type="checkbox"/> For some pts	<input type="checkbox"/> Not at all
Goal setting for group	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

Webannex 1b) Quality Assurance/Supervision Checklist for Peer Meeting (South Africa)

[To be administered by a member of the SMART2D team] Team member _____

A. Identification					
Group ID:	_____				
Date of meeting:	_____				
Meeting Number	____ / ____				
B. Attendance					
Number of participants expected to attend	_____				
Number of participants present	_____				
Number of CHWs present	_____				
Starting time	_____				
Ending time	_____				
C. Content					
Meeting topic:	_____				
Content covered:	<input type="checkbox"/> Fully <input type="checkbox"/> Partly <input type="checkbox"/> Not at all				
D. Process					
i. Some group activities are participatory*	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
ii. The strengths of each individual are identified**	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
iii. Individuals' goals are set	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
iv. Group goals are set	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
E. Peer Group Leadership					
i. PGL uses positive body language	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
ii. PGL is audible	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
iii. PGL is knowledgeable about the content	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
iv. PGL moderates all discussions	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
v. PGL empowers the members	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree

Pt / pts = participant, participants

* Such as small group / paired discussions / PGL ensures that everyone gets to say something

** Past healthy behavior, knowledge, other resources

Peer group observation: Rate on a scale of 0 [Not at all] – 10 [Yes] and comment

Question	Rate	Comments
Is the topic guide used to guide the peer group session?		
Is there active participation in the peer group session?		
Did the facilitator give participants the opportunity to share experiences?		
Did the facilitator give participants the opportunity to ask questions?		
If so, did the facilitator handle the questions adequately?		
Is the venue large enough to accommodate all participants?		

Overall comments

WEBANNEX PG2

Webannex 1c) Quality Assurance & interaction checklist for facilitator led phone sessions (Sweden)

Administered by: _____		Recordings to be attached _____			
Section 1. Identification					
ID#:					
Date of recording:					
Date of session:					
Section 2. Facilitator name					
Facilitator name:					
Starting time:					
Ending time:					
Total time of call:	_____ Minutes				
Section 3. Content					
Session nr:					
Content covered:	<input type="checkbox"/> Fully <input type="checkbox"/> Partly <input type="checkbox"/> Not at all				
Section 4. PARAS – Strength Based Behavioural Coaching					
1. The ft works with the pt to identify his/her strengths	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
2. The ft uses minimal response tokens (mm, etc)	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
3. The ft verbally reflects on pt talk	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
4. The ft gives sufficient time for pt reflection and responses	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
5. The ft summarises participant talk	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
Section 5. Ft/Pt interaction					
1. The pt shows interest in the session	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
2. The pt engages with the ft during the discussion	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
3. The ft moderates the session	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
4. The session holds a positive atmosphere	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
5. The pt voice opinions about the content of the session	<input type="checkbox"/> Strongly Disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
6. The pt shares experiences with the ft	<input type="checkbox"/> Strongly Disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
Section 6. Delivery of intervention					
1. The ft informed the pt about the content of the session	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
2. The ft discussed the goals/ tasks from last session with the pt	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
	<input type="checkbox"/> Not applicable				
3. The ft encouraged the pt to work on the session specific suggested tasks	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
4. The ft encouraged the pt to set goals (with or without their "Hälsokompis")	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
5. The ft adapts his/her speech/language so the pt can understand	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
6. The ft demonstrates knowledge pertaining to the content of the session	<input type="checkbox"/> Strongly Disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
7. The ft used the session guide to conduct the session	<input type="checkbox"/> Strongly Disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
8. The ft shows acceptance to pt ideas and behaviour	<input type="checkbox"/> Strongly Disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree
9. The ft gave the pt the opportunity to ask questions	<input type="checkbox"/> Strongly Disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neutral	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly Agree

participant, Ft = facilitator

References: Absetz P. Elämäntapaohjauksen toteutustavan vaikutukset ja valintaa selittävät mekanismit. 2019;23–8.

WEBANNEX PG3

Webannex 2. Care companion checklist (South Africa)

	SMART2D Home visits
name:	
date	notes:
	general wellbeing:
	goal setting and reviews
	nutrition:
	exercise :
	medications (received, adherence)
	Facility appointments (met, barriers etc)
	other (complications/other ailments)
	peer support group reminder:
	next CHW visit:
date	notes:
	general wellbeing:
	goal setting and reviews
	nutrition:
	exercise :
	medications (received, adherence)
	Facility appointments (met, barriers etc)
	other (complications/other ailments)
	peer support group reminder:
	next CHW visit:
date	notes:
	general wellbeing:
	goal setting and reviews
	nutrition:
	exercise :
	medications (received, adherence)
	Facility appointments (met, barriers etc)
	other (complications/other ailments)
	peer support group reminder:
	next CHW visit:

Webannex 3) Facility checklist to document (changes in) context

PROCESS TOOL 1: CARE CHECKLIST			
Site ID:			
Cluster ID: (To be filled in by research personnel)			
Evaluator (person to fill in list):			
Date:			
S.NO:	Question	Check: present, functioning	Comments
1.1: Basic Equipment			
A	Glucometers & strips		
B	HbA1C analyser & test		
C	Weighing scales		
D	Stadiometers		
E	Measuring tapes		
F	Blood pressure meter		
1.2: Guidelines			
A	Treatment guidelines		
B	Taskshifting guidelines		
C	patient flowchart		
1.3: Register			
A	Patient register		
B	Appointment diary		
C	Patient contact form		