# **BMJ Open** Intervention development of 'Diabetes Together' using the person-based approach: a couples-focused intervention to support selfmanagement of type 2 diabetes in South Africa

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#### ABSTRACT

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Objectives Type 2 diabetes (T2D) is a growing concern in South Africa, where many find self-management challenging. Behaviour-change health interventions are enhanced by involving partners of patients. We aimed to develop a couples-focused intervention to improve selfmanagement of T2D among adults in South Africa. **Design** We used the person-based approach (PBA): synthesising evidence from existing interventions: background research: theory: and primary qualitative interviews with 10 couples to ascertain barriers and facilitators to self-management. This evidence was used to formulate guiding principles that directed the intervention design. We then prototyped the intervention workshop material, shared it with our public and patient involvement group and ran iterative co-discovery think-aloud sessions with nine couples. Feedback was rapidly analysed and changes formulated to improve the intervention, optimising its acceptability and maximising its potential efficacy.

**Setting** We recruited couples using public-sector health services in the area of Cape Town, South Africa, during 2020–2021.

**Participants** The 38 participants were couples where one person had T2D.

**Intervention** We developed the 'Diabetes Together' intervention to support self-management of T2D among couples in South Africa, focussing on: improved communication and shared appraisal of T2D; identifying opportunities for better self-management; and support from partners. Diabetes Together combined eight informational and two skills-building sections over two workshops.

**Results** Our guiding principles included: providing equal information on T2D to partners; improving couples' communication; shared goal-setting; discussion of diabetes fears; discussing couples' roles in diabetes self-management; and supporting couples' autonomy to identify and prioritise diabetes self-management strategies.

# STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We used a rigorous and established methodology, the person-based approach, to develop and optimise Diabetes Together.
- ⇒ We used co-discovery think-aloud interviews to gather feedback on our intervention, that helped to model the intended intervention delivery context and stimulate discussion; this approach has not been used as part of the person-based approach before.
- ⇒ Our study promotion and outreach was constrained by the pandemic, and our recruitment rate was slower than expected; despite this, we captured couples representing the purposive sample that we sought.
- ⇒ We found that our participants had an expectancy of inevitable poor health as a person living with diabetes—this might impact general motivation to engage with any type 2 diabetes intervention: that was not addressed in our study.

Participants viewing Diabetes Together valued the couplesfocus of the intervention, especially communication. Feedback resulted in several improvements throughout the intervention, for example, addressing health concerns and tailoring to the setting.

**Conclusions** Using the PBA, our intervention was developed and tailored to our target audience. Our next step is to pilot the workshops' feasibility and acceptability.

# BACKGROUND

Type 2 diabetes (T2D) is growing in prevalence in sub-Saharan Africa (SSA).<sup>1</sup> While effective self-management can help control T2D,<sup>2</sup> a systematic review of diabetes



self-management practices in SSA showed only moderate adherence to diet and medication regimes, low adherence to physical activity, poor blood glucose monitoring<sup>3</sup> and poor levels of glycaemic control.<sup>4</sup> This suggests that, in addition to interventions that provide adequate access to healthcare,<sup>5</sup> effective self-management interventions are needed.

There is growing evidence that interventions targeting couples can achieve greater improvements in self-management of long-term conditions than interventions targeting individuals.<sup>6</sup> Specifically for T2D, relationship quality has been positively associated with diabetes outcomes, including perceived diabetes-related burden, engagement in self-management behaviours and glycaemic control.<sup>7–9</sup> A review of research in couples' coping with diabetes recommended that interventions focus on: shared understanding; discussing roles and expectations within the couple (including gender roles); exploring support perceptions and identifying which kinds of partner support are most valuable; and resolving concerns about intimacy and diabetes.<sup>10</sup>

Models for couples-interventions propose that shared appraisal of conditions (eg, perceiving diabetes as a joint problem)<sup>11</sup> and that communal coping is triggered by a 'transformation of motivation', leading to becoming more relationship-focused than individual-focused: partners become more cognitively and emotionally invested in supporting their partner's health by seeing health threats as behaviour change cues; sharing expectations for achieving health outcomes together; improving relationship functioning (eg, satisfaction and commitment); and improving positive communication styles.<sup>12</sup> Assisting couples in reaching this shared appraisal was an important part of our intervention.

Few couples-focused or family-focused interventions have been developed for T2D, but emerging evidence is encouraging. In the USA, a couples-focused intervention delivered by dieticians via telephone calls improved couples' communication,<sup>13</sup> which reduced diabetes distress and improved marital satisfaction. Other T2D interventions targeting patients and their families have found small positive effects on outcomes such as glycaemic control, beliefs about diabetes, psychological well-being, diet and exercise.<sup>14 15</sup> We are aware of several other couples-focused interventions being evaluated for T2D outside SSA (eg, studies by Moore *et al*<sup>16</sup> and Liao *et al*<sup>17</sup>) but these have not yet published outcomes.

There have been couples-focussed interventions for other health behaviour change, for example, uptake of HIV testing. Studies conducted in KwaZulu-Natal (involving NMcG), South Africa, developed a highly effective couples-focused behavioural intervention, involving two group workshops and four couples counselling sessions, to promote uptake of couples HIV testing.<sup>18–20</sup> We draw on these experiences and the group workshops and couples counselling session format to provide the T2D couples-focused framing for our intervention development. This evidence combined suggests that a couplesfocused intervention to provide support with behaviour change and communication skills in managing T2D may be a welcome and feasible approach. Thus, we aimed to develop materials for face-to-face workshops (henceforth 'the intervention') as part of a couples-focused intervention to support T2D self-management, focussing on helping the couple to transform their appraisal of health concerns to shared management through provision of clear and accurate information, motivation, communication support and skill-building.

In this paper we describe combining theory and literature with current T2D interventions and formative interviews with the target population to plan the intervention (Phase 1). Then we prototype and iteratively optimise the intervention using feedback from the target population (Phase 2).

# METHODS

# Approach

We used the person-based approach (PBA) for intervention development, which aims to understand the experience of the target audience while incorporating theory, evidence and qualitative work.<sup>21</sup> This results in high-quality interventions that are highly engaging and persuasive, because they are routed in understanding and overcoming barriers to behaviour rather than simply providing advice and guidance. In Phase 1 of our study, this involved conducting interviews with people living with diabetes (PLWD) and partners about their perceptions and experiences of living with T2D, and synthesising this with theory to understand the barriers and facilitators to good diabetes management in the target group. This led to the development of specific 'Guiding Principles'-a set of guidelines that we use to decide what material should be in the intervention-and a logic model that demonstrates how the intervention should result in improved diabetes management.

In Phase 2, we prototyped the intervention using existing interventions as our starting point—always referring back to our guiding principles to select the most appropriate content and behaviour change techniques—and used iterative co-discovery think-aloud (TA) interviews with PLWD and their partners to optimise the intervention. Figure 1 shows the phases of intervention development. The 'Standards for Reporting Qualitative Research' checklist<sup>22</sup> is given in online supplemental appendix A.

# Setting

The study took place in Cape Town, South Africa. Historically, the South African healthcare system is highly fragmented, with discriminatory effects between racial groups.<sup>23</sup> The impact of this system is still evident today<sup>24</sup>: despite constitutional prioritisation of high-quality healthcare,<sup>25</sup> poor standards of care have resulted in a mistrust of the public healthcare system.<sup>26</sup> Further, South

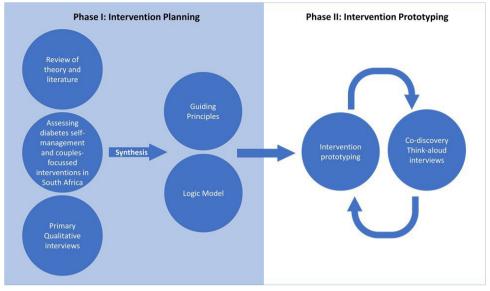


Figure 1 Intervention planning and optimisation for Diabetes Together.

Africa's health system is complicated by its public/private organisation, which makes the health system highly unequal. More than 80% of South Africans seek health-care through the public, state-funded health services.<sup>27 28</sup>

Our participants and Community Working Group (CWG) were recruited through informal connections and public clinics within and around townships with a predominantly black African population, including Khayelitsha, Gugulethu and Langa. These low-income neighbourhoods face an array of challenges such as poverty, high rates of unemployment and inadequate infrastructure<sup>29</sup> in both formal (eg, apartment building) and informal (eg, shack) housing.

# Patient and public involvement

The CWG was made up of PLWD and their partners who responded to our advertisement for volunteer members. They gave sustained input during the development process, and two public and patient involvement (PPI) representatives volunteered to join the development team. This enabled the specific psychosocial needs of the target users to be understood and relevant contextual behavioural barriers to be addressed. We plan to share our findings with the CWG once we have finalised and evaluated our full intervention.

Access to clinics was granted by the Western Cape Department of Health.

# Phase I: intervention planning

We undertook five primary intervention planning activities to explore barriers and facilitators to good T2D selfmanagement: defining intervention target behaviours; collating evidence from the literature; collating materials from existing interventions; conducting qualitative interviews with the target population on perspectives and priorities relating to T2D self-management; and planning the intervention using the PBA.

# Phase 1: sampling and recruitment

For the activity of conducting qualitative interviews with the target population on perspectives and priorities relating to T2D self-management, a sample of PLWD were identified, recruited and interviewed by members of the research team in South Africa, including BM-D, NMb and MVP. Participants eligible for Phase 1 were adult couples in a relationship for at least 6 months (not necessarily sexually active) where one person had a T2D diagnosis and attended routine public sector care, used by 80% of South Africans.<sup>27</sup> Recruitment for Phase 1 took place between June 2020 and February 2021. Initially, recruitment from clinics was planned, but during the COVID-19 pandemic, clinics paused research support. Latterly, despite changing COVID-19 guidance and approval for recruitment at the clinics, clinical staff remained too pressed to assist in recruitment. Instead, we used a 'snowballing' method: adverts were shared with appropriate contacts who were then asked to share these adverts with their contacts. In this case, we leveraged our CWG and other community-based networks. When potential participants had been identified, before being invited to the interviews, demographic data was collected to purposively sample by age; gender; language spoken in the home; duration of current relationship; and whether their diabetes was diagnosed before or during their current relationship (eg, we wanted to ensure we recruited both male and female PLWD, so that our interviews represented viewpoints from people with diverse characteristics). Partners were recruited by providing the PLWD with an invitation to the study and asking them to ask their partner to contact the study team. When the partner contacted the study team, they were screened for eligibility and, after providing informed consent, interviewed separately and their demographic details recorded. The topic guides for these interviews (see online supplemental appendix B) were developed by experts on T2D care and couples

research, informed by our literature review and focused on barriers and facilitators to T2D self-management as a couple. The interviews of the PLWD and partner were conducted in isiXhosa or English, translated where applicable and transcribed into English. Each participant was reimbursed ZAR150 (£7.49 on January 1 2021) for their time.

# **Qualitative analyses**

KAS analysed the interview data using a mixed inductive/deductive thematic analysis<sup>30</sup> to identify barriers and facilitators to diabetes self-management. Thematic analysis involved reading through the transcripts thoroughly and assigning codes to sections that describe what participants were saying. These codes were refined, combined and improved through iteration and discussion. Regular discussion of emergent themes with the interviewers and expert research team ensured that they reflected the contents of the data.

# Phase II: intervention development and optimisation

Phase II aimed to develop materials for two half-day workshops and optimise the materials through iterative feedback from couples representing the target population. This involved creating the intervention prototype and refining the prototype using feedback from TA interviews with participants.

# Creating the intervention prototype and videos

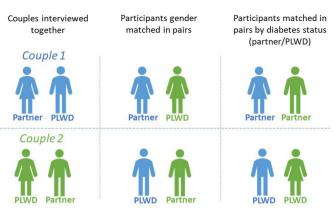
Workshop content was drafted in multiple stages. Building on Phase 1 learnings, the research team (consisting of experts in behaviour change, diabetes self-management, couples-focused interventions and implementing interventions in South Africa) identified the topics to be covered in the workshops. Second, the content was drafted as text (building on materials from Phase 1), following the guiding principles.

As the intended intervention included face-to-face facilitated workshops with groups of couples, we created videos representing how we anticipated delivering each section of the workshop. This would allow participants to give feedback in a more naturalistic way (watching a presenter and slides, with the opportunity to discuss and ask questions) than reading an intervention section outline, and standardised content delivery. Each section was developed iteratively, with input from the research team and feedback from the TA sessions, with several modules also presented to the CWG. Potential changes were discussed, and the content modified and iterated over several times, always using the guiding principles as our rubric for what should be included.

# **Phase II: TA sessions**

# Recruitment

Recruitment for Phase 2 used in-clinic recruitment in addition to the outreach strategies used for Phase 1, and the same eligibility criteria and enrolment procedures. This was because COVID-19 restrictions had by this time been relaxed and clinics were once again engaging in



**Figure 2** Participant pairings for co-discovery think-aloud interviews. PLWD, people living with diabetes.

research activities. The TA sessions took place between August 2021 and January 2022 and were conducted by NMb and MVP.

# Procedure

The co-discovery TA method allows participants to explore and discuss elements of an intervention together, with minimal prompts, and reflects the intended setting of group delivery of the intervention.<sup>31</sup>

We planned to deliver parts of the workshops to different subgroups of participants: separating partners and PLWDs for 'stress management' and 'fears and complications'; and then separating women and men to discuss 'sexual relationships' and 'gender roles'. All other sections of the workshops were delivered to couples together. To conduct the co-discovery TA sessions, we paired participants as follows: (1) with their own partner, (2) matched with another PLWD/partner or (3) matched with the same gender (see figure 2).

We intended to conduct the TA sessions at four time points, including two couples at each time point. Sections that significantly changed based on feedback from interviews were included in subsequent interviews for further feedback. Typically, two interviews were conducted simultaneously, swapping pairings between sections. A single couple attended the fourth TA session, so a fifth session was conducted with two new couples.

Recruitment was slow during 2021 and we wanted to make the best use of participant time, so rather than a pilot, KAS, a researcher with extensive experience conducting TA interviews, provided training to the interview team and held post-interview debriefs and ongoing review of the early recordings to provide further guidance.

Recruited couples were invited for a single TA session at the research centre. After informed consent was obtained, pairs of participants viewed a video of a researcher (KAS or MVP) presenting slides of a section of the workshop materials in the presence of an interviewer (MVP or NMb). The interviewer provided translation (isiXhosa) if requested. Participants could pause and rewind as they liked. The interviewers probed for feedback throughout the session and requested specific feedback from a topic guide (online supplemental appendix B). Where appropriate, participants swapped pairings to view different sections of the intervention. TA sessions were conducted in English or isiXhosa, audio recorded and transcribed into English. They were then analysed using the Table of Changes<sup>32</sup>: a technique for rapid inductive qualitative analysis where positive and negative comments are tabulated for each workshop section to identify barriers and problems affecting intervention efficacy so that improvements can be identified and prioritised.

# RESULTS

#### Phase I

#### Defining intervention target behaviours

Based on South African clinical guidance<sup>33</sup> and diabetes care expertise and research experience within the team (BM-D, NL and PD), the research team agreed that the intervention should focus on motivating the following behaviours: (1) Improve treatment adherence (blood glucose monitoring where applicable, self-monitoring for complications and clinical attendance; appropriate use of medication); (2) Improve diet (increasing fruit, vegetables and wholemeal products; and reducing refined carbohydrates and saturated fats); and (3) Increase physical activity.

# Collating and synthesising evidence *Literature review*

Two core papers summarise the findings of research into diabetes management from a couples' perspective:

Lister *et al*'s narrative review<sup>10</sup> of 49 papers indicated that several core themes should be considered when designing interventions to support couples' diabetes self-management: helping the partner to reach a shared understanding of T2D management; reaching shared expectations of sexual functioning; facilitating empathic social support from the partner; ensuring that gender roles are reappraised to prevent women from being overburdened. Negative couples' communication factors include hiding concerns; avoiding conflicts; nagging; poor communication; low warmth coupled with high emotional involvement; and, criticism. Generally, poor relationship satisfaction was associated with poor diabetes self-management.

Gupta *et al*<sup>44</sup> assessed 66 articles to review the impact of family and partner support on diabetes care. They found that the partner plays a key role in PLWD overcoming negative behaviours and adhering to healthy lifestyle behaviours and listed the following factors as influencing diabetes outcomes: lack of knowledge; personal organisation; financial constraints; lack of social support; negative mood; poor experiences of diabetes; and poor interaction with the healthcare system. Similar to Lister *et al*,<sup>10</sup> they proposed that family have a facilitatory (eg, encouraging eating a better diet), obstructive (eg, refusing to accommodate healthy food choices) and equivocal behaviour (eg, medication reminders that may be perceived by some

PLWD as nagging) that interact with personal diabetes management behaviour.

# Primary qualitative interviews

Twenty interviews were conducted with 10 couples where one partner had T2D (5 couples with one female PLWD; 4 couples who spoke English and Afrikaans and 6 couples whose primary language was isiXhosa, with a median age of 51.5 years (IQR 42.8–60.3). The following themes were identified:

#### Knowledge

Both PLWD and their partner reported incomplete knowledge about diabetes, and a desire to learn more. Where they had received information from healthcare professionals, they were more confident in terms of self-management.

The nurses are very supportive even when he comes back from the clinic he never came back with complaints. (female partner)

# Fears

Both PLWD and their partners reported fears of the consequences of diabetes, including death during sleep, blindness, amputation and collapses:

Yes, there are moments that it comes into my mind that maybe if I go to bed maybe it can be my last day today that I sleep on this bed [die]. (female PLWD)

Partners and PLWD differed in how they framed these fears: PLWD expressed their fears in terms of what they experienced, while partners talked about coping with the consequences of the feared situation:

When his sugar level goes very low...Then I have to struggle to get him awake and get him some sugar water... It is actually very difficult, but um, because when you get older, because it is very heavy to lift him up by one arm and try and get him up to get his sugar water down his throat with the other arm. So it takes about a few days for my muscles to recover again. (female partner)

It is a very scary situation, when your blood sugar goes low and you do not know if you are going to come back again and your partner is also very scared... sometimes she tries to give me sugar water and I am pushing her away that glass of sugar water, and I don't want it, just leave me alone, and I mumble that. But she forces that I must take it. And then I am coming back again. And that is bringing me back to life. (male PLWD, partner of above)

# External stressors

Female participants often had caring responsibilities for children and reported busy lives. Both men and women experienced external stressors including lack of money and employment, and (at the time of interview) disruption of services due to COVID-19. COVID changed everything because we are not working, companies have closed, work is scarce. Sometimes he gets small jobs and it is not so bad. (female partner)

#### Substance use

Substance use by either member of the couple, especially alcohol use, was a frustration for couples, who understood it was particularly bad for the health of PLWD:

I become worried. I will ask "did you take your medication"? "Did you take them"? Because I am concerned that they don't correspond with alcohol. (Male partner)

#### Moods

PLWD also reported that they experienced low moods that made them irritable. Partners reported noticing a change of mood and adopting strategies to reduce conflict:

There is some moodiness at times. And some stuff on his mind. But I try not to think that much, because maybe it is just mood swings. And I just try to look over them and continue what I am doing. (female partner of PLWD)

#### Food and physical activity

Participants reported a positive attitude to engaging in physical activity when they felt well. Food choice was reported as stressful for the couples. PLWD and partners reported awareness that PLWD should eat less sweet food. Both male and female partners and PLWD raised anxieties about ensuring suitable food was always available:

She is always worried about what to cook, what to eat, she stresses too much about food. She does not like to be hungry. I don't know whether it is because of diabetes, but there must always be food. (male partner of PLWD)

#### Libido

Participants reported reduced libido in PLWD (both men and women), especially when the PLWD reported poor diabetes self-management. This resulted in stress within the relationship. For men, this was a source of frustration—while women reported acceptance of reduced sexual activity:

It is hurting to an extent that we end up having a quarrel (...) When I am in the mood for sex then she will tell me that she is not interested. (male partner of PLWD)

Overall, this evidence reflects findings of the literature.<sup>10</sup> Couples who reported collaborative management of diabetes, a more supportive relationship and better knowledge of diabetes perceived they had better diabetes control, even if they still experienced low blood sugar events and periodic hospitalisations.

# Existing interventions

In addition to the interviews and literature review, we examined existing interventions used to improve T2D selfmanagement in South Africa. We conducted a literature search for T2D interventions in South Africa and found three. We collated the features of two T2D interventions conducted previously by members of the Chronic Disease Initiative for Africa (CDIA), targeting individuals with T2D or at risk of T2D based in Cape Town, and a diabetes management booklet, the 'Diabetes Toolkit'<sup>35</sup>; this was previously designed by one of the researchers (BM-D), an established patient-facing diabetes educator for clinicians and patients in Cape Town.

The peer group programme component of the 'Self-Management and Reciprocal learning for the prevention and management of T2D' (SMART2D)<sup>36</sup> study, involved nine group workshops for PLWD; the 'Living Great with Diabetes' (LGD) programme,<sup>37 38</sup> delivered as four to five 1-hour group workshops for PLWD.

The peer group programme component of SMART2D, LGD and the Diabetes Toolkit<sup>35 36 38</sup> provided basic information about diabetes, including its physiology, causes and treatment. They also provided information about the benefits of physical activity and motivation to engage in it. All three resources provided South African diet guidelines, including food groups with culturally specific examples and portion sizes, information on medication, glucose testing and the symptoms of hypoglycaemia. The impact of substance use on health was mentioned in all three interventions. Two interventions mentioned complications, self-monitoring, attending check-ups, stress and mental health management, while sexual health was only mentioned in SMART2D.

#### Developing guiding principles

We compiled all the evidence from Phase 1 to identify the barriers and facilitators for diabetes self-management within this population. This led to the development of guiding principles using behaviour change theories—*how* we would overcome barriers that are important to the intervention context and motivate participants to perform the target behaviours.

Barriers were categorised using the COM-B (Capability, Opportunity, Motivation, Behaviour) model<sup>39</sup> into psychological capability (understanding and remembering what to do); physical opportunity (having the money, time and equipment) and social opportunity (avoiding peer pressure to drink, eat unhealthily); autonomic motivation (difficulty in changing communication styles), and reflective motivation (eg, 'unhealthy food tastes good').

Barriers identified using interdependence theory<sup>12</sup> were lack of awareness of health threats; lack of shared motivation to overcome health issues; and poor relation-ship quality and communication.

This mapping led us to match appropriate behaviour change techniques to address these barriers from the behaviour change technique taxonomy.<sup>40</sup> We then examined interdependence theory<sup>12</sup> to identify all positive

behaviours that were aligned with the guiding principles that were missing, and added them to our model, to increase its chance of effectiveness.

The guiding principles were used as our core document to refer to when deciding on what content should be included in the intervention—if a proposed feature was evidence-based and supported a guiding principle, it was included.

Table 1 summarises the agreed guiding principles, showing the key barriers and facilitators from literature and our interviews that led to their inclusion. A full summary table of barriers, facilitators and content recommendations can be found in online supplemental appendix C.

Concurrently, we developed a logic model to explain how the intervention would work, that is, by illustrating how the mediators (eg, decreased stress, increased physical activity) would influence T2D self-management (figure 3). Improving knowledge about diabetes and self-management provides PLWD and partners with a rationale for performing target behaviours. Providing information to the partner helps them recognise and appraise diabetes self-management as a shared concern while motivating ongoing support to the PLWD fostering mutual understanding. Modelling successful diabetes self-management (eg, providing contextually relevant examples) improves positive outcome expectancies (ie, belief that target behaviours have positive outcomes) and self-efficacy. Raising awareness of gender roles within relationships helps to guide couples to reappraise possible changes that could be made for collaborative diabetes self-management. Providing couples communication skills training enables couples to enhance their discussions regarding diabetes self-management challenges and make plans. These processes positively impact the purported mediators: diabetes self-management behaviours and relationship quality, leading to better perceived health and reduced stress, thereby motivating improved diabetes self-management. In turn, this improves the primary outcome, T2D control and related secondary outcomes.

#### Phase II

#### Synthesising materials

Guided by our guiding principles, we combined evidence from the qualitative interviews, theory, existing interventions and literature, into the following initial workshop components: information about diabetes (including medication and self-management), diet; physical activity, substance use, stress management, fears and complications, sexual health and gender roles; and building goalsetting and couples' communication skills.

We subsequently considered what changes might be appropriate for our intervention as a couple-focussed intervention. Our interviews suggested that PLWD and their partners think differently about fears; partners avoid confrontation with PLWD experiencing low mood; and men and women have different perspectives on sexual intimacy and family care. As South African men and women seem more comfortable discussing sensitive topics in single-gender group,<sup>19</sup> and evidence indicates that partners avoid discussing upsetting subjects with their partners (especially if they are ill or fragile<sup>41</sup>), we decided to split couples into separate groups for several topics. First, by diabetes status (PLWDs separate from partners) for discussion of fear and stress management; second, by gender for discussing sexual relationships and gender roles. By doing this, we intended to provide a space without partners to discuss sensitive issues and to motivate making concrete plans to address sensitive subjects with their partner.

#### Creating the intervention prototype and videos

In this step, the topics in the evidence synthesis were turned into workshop content, incorporating the behaviour change elements proposed by our guiding principles (table 1). Furthermore, we could not simply copy the intervention content verbatim, as no intervention had been developed for couples—we needed to refactor to make the content suitable for couples.

Several resources were used as bases for the intervention: we chose to adapt UK-based behaviour change interventions on Healthy Eating and Physical Activity that KAS had developed<sup>42 43</sup> (the central activities, advice and format matched our guiding principles and has been found to be robust enough to adapt to different contexts, eg studies by Bradbury *et al*, Essery *et al* and Rowsell *et al*<sup>12–44</sup>); the diabetes interventions reviewed in Phase  $1^{35 36 38}$ ; and communication skills delivery inspired by the speaker–listener technique<sup>45</sup> in HIV-focused couples' studies.<sup>18 19</sup> To model intended behaviour change, we created 'Stories from Example couples'—four fictional couples overcoming challenges of T2D, referred to throughout the workshops.

The first of the two half-day workshops covered less sensitive subjects, so participants could build rapport, and prioritised detailing the target behaviours—improved treatment adherence, diet and exercise. The workshop provided clear and accessible information about managing diabetes, diet, exercise and goal setting. Couples' communication was demonstrated by an audiorecorded role-play by KAS, an interactive role-play and a handout. For TA sessions, the interactive role-play was represented by a role-play video.<sup>46</sup>

The second workshop addressed more sensitive topics: substance use, stress management, fears and complications, sexual relationships and gender roles. Goal setting and goal reviewing, and communication skills were also revisited in this workshop.

Each section of both workshops contained a mixture of didactic elements and participatory elements, such as quizzes, discussion points, a mindfulness exercise, roleplay and goal setting/goal review activities.

Example modifications in the initial drafting stage were: simplifying language; emphasising the importance of self-monitoring of foot sores and eyesight; removing

# Table 1 Intervention guiding principles

		Relevant behaviour		Evidence (B=barrier;
Intervention guiding principles	Intervention features	change techniques <sup>39</sup>	Interdependence theory	F=facilitator)
<ol> <li>Providing information and advice on diabetes self- management.</li> </ol>	Information on diabetes provided by credible sources.	4.1. Instruction on how to perform the behaviour.	Shared understanding— putting both partners on a level footing regarding	Lister: F: a shared understanding of type 2 diabetes
Increase understanding about diabetes self-management, effectiveness of treatment and lifestyle changes for people with diabetes and their partners. This includes learning what diabetes is, and the importance of medication, healthy eating and exercise, etc.		5.1. Information about health consequences.	knowledge of diabetes self-management.	management.
		5.6. Information about emotional consequences.	Shared motivation – provide information on health consequences	Gupta: B: Lack of knowledge.
	Information on health outcomes of poor/good diabetes self-management.	9.1. Credible source.	of good diabetes self- management.	Interview: B: Incomplete knowledge.
	Information on the emotional consequences of good diabetes self-management.			
2. Helping couples to talk about diabetes together. Help couples communicate	Guidance on good communication techniques for discussing difficult subjects.	6.1. Demonstration of the behaviour.	Communication skills training.	Lister: F: Empathic support. B: Poor couples
clearly with each other about diabetes and come to a shared		6.2. Social comparison.		communication.
understanding of diabetes self- management. Eg, stating clearly	Role-play of an argument using poor and good couples' communication.	8.1. Behavioural practice/ rehearsal.		Gupta: F: Good familial support. B: Poor familial support.
	Reflection on the role-play.	8.3. Habit formation.		Interview:
	F: G	F: Good couples communication.		
3. Helping couples get motivated to set goals together. Help couples reach a shared motivation to look after their	Use SMARTER (Specific, Measurable, Accountable, Realistic, Timed, Evaluated and Reviewed) goal setting	Specific,1.1. Goal settingGupta:ountable,(behaviour).B: Poor personalEvaluatedorganisation.	B: Poor personal	
health together and agree on goals relating to diabetes self- management.	Ith together and agree onto choose a diabetes self-Is relating to diabetes self-management goal and plan.	1.2. Problem solving.		
Goal r	Goal review and revision in Workshop 2.	1.4. Action planning.		
		1.5. Review behaviour goal(s).		
		1.6. Discrepancy between current behaviour and goal.		
4. Helping partners to share fears and cope with hard times. Helping people with diabetes and partners to express their	Guided discussion on fears and complications of diabetes.	3.2. Social support (practical).	Provide a discussion forum for people to express their fears about diabetes away from their partner so they	
fears to their partner about future diabetes-related complications and death.	to their partner about future Stress management 3.3. Social support can gain measures related complications suggestions. (emotional). encourager	can gain motivation and encouragement to discuss it with their partner.	Interview: B: Fears.	
	Instruction and practice in short mindfulness techniques.	4.1. Instruction on how to perform the behaviour.		
		8.1. Behavioural practice/ rehearsal.		
				Continued

Table 1 Continued

Intervention guiding principles	Intervention features	Relevant behaviour change techniques <sup>39</sup>	Interdependence theory	Evidence (B=barrier; F=facilitator)
5. Acknowledging how gender plays a role in diabetes care. Encourage couples to discuss the traditional gender roles in	Guided discussion on impact of gender on diabetes self- management.	3.2. Social support (practical).	Provide a discussion forum to hear and explore alternative roles as a man or woman in the	Lister: B: Female care burden.
their relationship in relation to diet and care for diabetes, and things that they could change to make diabetes self-management easier for example, cooking.	Prompt ideas and planning of how things could change.	<ul><li>3.3. Social support (emotional).</li><li>1.4. Action planning.</li></ul>	relationship and be able to discuss this with a partner.	
6. Remembering that all couples are different: supporting couples to make choices that fit their lives. Acknowledge the impact of the wider environment on the couples' diabetes self-management	Do not be prescriptive—allow couples to explore their own barriers and choose their own goals to improve diabetes self- management.	(None-to provide emphasis on choice and discussion throughout.)	Encourage participants to reflect on what they want their role to be in diabetes self-management and discuss with their partner to reach an agreement of	Gupta: B: Poor experiences of diabetes. B: Financial constraints.
choices. This includes money and employment, age, household situation, multimorbidity, etc.			mutual roles.	Interview: B: External stressors.

unnecessary activities from long sections; modifying 'Talking Points' sections to focus on T2D self-management; modifying foods to match the South African diet; adding more examples; adding a mindfulness exercise; emphasising the dangers of drinking alcohol, particularly for PLWD; and refining presentation of the couples communication skills section to make it easier to understand (see online supplemental appendix D for an example, and table 2 for a summary of modifications).

The "Template for intervention description and replication" (TIDIER) checklist for intervention reporting (<sup>47</sup>; online supplemental appendix E) provides further details of final workshop content.

# TA sessions

Nine couples (median age 48.5; IQR 45–55.8) participated in the TA sessions—five male PLWD, and eight couples' primary language being isiXhosa. Interviews were conducted in either English or isiXhosa. Participants viewed four to nine sections in an interview. Online supplemental appendix F highlights which sections were reviewed in each TA session.

The material in all sections was reported to be relevant and acceptable to all participants—all participants felt that all sections had value. There was no explicit negative feedback that any section was poor or irrelevant, despite

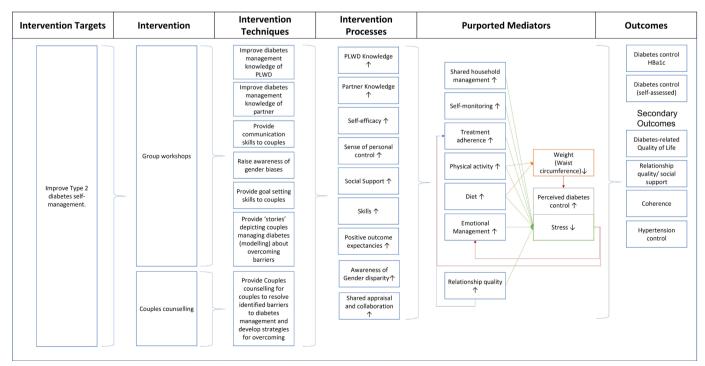


Figure 3 Logic model for Diabetes Together. HbA1c, glycated haemoglobin; PLWD, people living with diabetes.

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Section	Number of iterations	Source material	Summary of changes	
Stories from example couples	4	None	Added photos, swapped photos to match demographic of target group, changed ages, simplified wording.	
Diabetes information	4	Diabetes Handbook, SMART2D, Living Great with Diabetes	Reduced true/false statements, changed examples, provided and emphasised self-monitoring and check-ups, used low blood sugar/hypo for hypoglycaemia, clarified information on injectable insulin and side effects, simplified explanations.	
Physical activity	4	Active Brains; Renewed	Removed expensive activity examples, added 'Choosing Ways to be more active' and 'Tips and Tricks', added information on 'recovering from injury' and information on breathlessness.	
Healthy eating	6	Active Brains; Renewed; POWER; Diabetes Handbook, SMART2D, Living Great with Diabetes	ok, other people, changed wording, changed answer format, made exam more culturally relevant.	
Substance use	3	Diabetes Handbook, SMART2D, Living Great with Diabetes	Simplified how alcohol affects diabetes management; changed the message from 'drinking safely' to 'think about stopping'; changed the discussion point to focus on alcohol.	
Couples' communication	4	Speaker–listener technique	Formulated into five steps, added video of example role-play for TA sessions only, added a summary page.	
Fears and complications	3	Living Great with Diabetes	Added examples of complications, added pictures to stories.	
Stress management	3	SMART2D	Added mindfulness exercise, changed framing of mindfulness to be about relaxation and breathing, re-ordered sections.	
Sexual relationships	3	SMART2D	Added pictures to couples' stories, modified talking points, updated the further resources list.	
Gender roles	7	Developed from literature	Expanded gender and power questions, removed exercise, simplified wording, added talking points, added more relevance to diabetes, removed reference to power, modified example stories.	
Goal setting	1	Igugu Lethu	Unmodified.	

explicit probing for criticism. Overall, both PLWD and partners were very positive about receiving information about diabetes self-management, which was not consistently offered to PLWDs, and rarely provided to partners:

So being here today and receiving all this information has been very useful and this is information that we do not have regular access to. I think that we need more of these. (male partner, TA4)

The materials effectively stimulated discussion between participants who did not know each other, providing a supportive atmosphere to discuss sensitive topics, such as insecurities about men being unemployed and unable to provide income for their household, or sexual dysfunction for women and men:

Because what we are trying to avoid ... we don't want them to think 'our wives will go outside and cheat on us...' because them with their diabetes, it is lowering their self-esteem... And for them to have no money, not to provide... is killing them slowly, inside... and we know we have to do whatever has to be done ... as women. (female partner, TA5)

Participants recognised the value of being able to talk with other people, without their partners, about their stresses and to share advice:

It is easier to share stories with a stranger.... You can talk anything, ask anything. (female partner, TA5)

They also recognised the importance of communication with their partners to keep a relationship stable:

Communication is key. It's a key like this, it helps to solve problems. (male PLWD, TA2)

Critical comments and misunderstandings of intervention content prompted to make some changes. For example, making diet recommendations included local foods, adding reassurance on breathlessness and dangers of injury from physical activity to the physical activity page, promoting discussion of issues with partners, adding stress management tips, strengthening the option of 'Stopping Drinking' and providing simpler explanations of what diabetes is and how it interacts with substance use. These sections were modified in response to the feedback. It was also found that the 'Gender Roles' section, while stimulating discussion, did not generate discussion about diabetes-related issues, so we modified the section to give stronger examples of the changes that diabetes might have on gendered roles, such as women taking on more paid work and men being more active in household/caregiving tasks.

As the pairs were looking at different content areas, they raised some questions addressed in content they had not seen. This provided further support that the unseen content was necessary and emphasised the need for a workshop schedule in the full intervention so that participants could see what topics would be covered and be reassured that their questions would be addressed.

See 'online supplemental appendix G: Phase 2 Table of Changes: Negative Comments' for a list of comments and changes. Positive comments were numerous but general statements such as 'I like it' and thus are not shown.

#### DISCUSSION

Using the PBA that combines theory, primary qualitative evidence and learnings from similar interventions in South Africa—we created 'Diabetes Together,' the first couples-focused intervention that aims to improve diabetes self-management in South Africa. We then used rapid iterative co-discovery TA interviews to make iterative improvements to the intervention, resulting in an intervention optimised for the target couples.

Our approach ensured that workshop content was robustly developed. Our formative work echoed the themes of Lister *et al*,<sup>10</sup> especially concerning the importance of good communication. While we found that the emphasis and framing of certain concepts (eg, preference for a 'stop alcohol use' message over 'reduce alcohol') did require tailoring for the target community, the core messages remained largely universal—knowledge of diabetes, guidance on self-management, support for couples' communication and goal setting, substance use, managing stress and diabetes fears, concerns over sexual relationships and gender disparities were all found to be important to address.

Our intervention fundamentally differs from previous diabetes interventions by involving partners in T2D selfmanagement. Partners in our study expressed a lack of knowledge about diabetes self-management, and both PLWD and partners experienced communication problems. We theorise that our approach involving the partner as a collaborator in a shared health concern motivates and supports sustained behaviour change more than solely focussing on the PLWD. Moreover, engaging partners in healthy behaviour change may support sustained behaviour change by the PLWD.

#### **Study limitations**

This study took place in 2020-2022, during the COVID-19 pandemic. This presented numerous logistical challenges to the study team, in particular around study recruitment by phone and online. People with a low income may use multiple sim cards to retain good coverage, and change numbers frequently; pay-as-you-go is typical, so people may avoid enabling mobile data and making outgoing calls.<sup>48</sup> Thus, online recruitment for this target population is potentially selective. Recruitment for Phases 1 and 2 was subject to changes in local pandemic restrictions over time. This resulted in most Phase 1 interviews being conducted over the phone and the timelines of the project being extended. Our recruitment rate may also have been impacted by national advice that PLWD were at increased risk of severe disease if they acquired SARS-CoV-2-potential participants may have been hesitant to volunteer.

Data collected in both phases of the intervention development may also have been coloured by participants' experiences of the pandemic—for example, increased stress regarding employment and fears of catching the virus. Our data potentially reflects couples' experiences of diabetes in a more stressful situation than 'normal'.

In our formative interviews, participants reported confidence in their diabetes self-management, while also reporting indicators of poor management. This implies that low expectations of the outcomes of good diabetes management could impact desire to engage in an intervention, for example, PLWD do not recognise the significant health improvements that could be made and accept poor health as inevitable. Wider community education could help address this perception.

#### **CONCLUSIONS**

Using the PBA ensured that we developed an intervention rooted in the concerns of our target community, based on the importance of promoting couples' shared appraisal and collaboration in the self-management of T2D. We are confident that 'Diabetes Together' contains appropriate and persuasive content to help couples make and sustain (healthy) lifestyle changes to improve T2D self-management. The next stage is to pilot the intervention for feasibility and acceptability.

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**Contributors** NMcG, NL, BM-D and KAS designed the study. KAS analysed the qualitative data, prototyped the intervention, provided support and guidance to the team in South Africa and wrote the first draft of the paper. MVP and NMb conducted qualitative interviews, contributed to writing the paper, supported data analysis and prototyped the intervention. BM-D conducted qualitative interviews and provided recruitment support and expert advice. PD provided oversight and guidance on the intervention development and administrative processes. NL and NMcG led the project team in South Africa and UK, respectively, providing support and guidance throughout the project. NMcG is the guarantor of the work in this paper.

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