PROTECTOR PILOT REPORT

Results, learnings, and recommendations

9 February 2024

PERCEPT

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Executive summary

The PRO-Active TElemedicine TaCTical OpeRation (PROTECTOR) programme was a telehealth pilot intervention to support people living with poorly controlled diabetes. The aim of the intervention was to ascertain whether a short telehealth-delivered intervention could help patients to improve their diabetes control and self-efficacy and bring their measures (such as HbA1c) closer to clinically normal ranges. For patients identified as per the eligibility criteria, a coordinator conducted a 'baseline survey' for those who agreed to participate. The intervention had two distinct phases: intensive and maintenance. During the intensive phase, the telehealth doctor called the patient every weekday for two weeks with the aim of optimising their glucose control through medication adjustment. The maintenance phase lasted 8-10 weeks and the telehealth doctor called patients once per week for the first two weeks to check on their glucose control and provide further education and support. After two weeks, the telehealth doctor called the patient fortnightly with the same aim. Once the maintenance phase was over, patients were graduated from the programme and referred to Hanover Park CHC to have their exit HbA1c measures taken. After the HbA1c blood tests were done, the telehealth surveyor called the patient for an endline survey to find out about their experience of the intervention, and the perceived benefits or drawbacks.

PROTECTOR was measured using the following outcomes:
1. Process measures
2. Clinical outcomes as per best practice norms
3. Patient-reported outcomes and patient-reported experience as designed for the intervention
4. Qualitative interview findings
5. Economic evaluation (of the pilot and the intervention at scale)

The headline findings from the intervention were that of the 82 patients who completed the PROTECTOR pilot, **the median change in HbA1c was 2.66 percentage points lower than their starting HbA1c level.** This is a substantial result, given the relationship between lowering HbA1c levels and decreasing the risk of diabetes-related complications which are traumatic for patients and their providers, and costly to the health system.

To determine the cost of scaling up PROTECTOR, the team developed an organogram and optimal patient load for a virtual clinic. If scaled up for the entire province (for patients with uncontrolled diabetes, HIV or Tuberculosis), the province would need to fund three virtual clinics at an additional cost of R16m. However, the return on investment was also calculated by determining the estimated savings due to averted health complications. Using two scenarios, one an average cost for all diabetes-related complications, and the other cost for only myocardial infarctions, we quantified the potential savings to the system. Even with a R16m outlay, the province would look to save between R63m and R139m, **a return on investment of 284%-784% per year**.

These savings could be used to either free up hospital bed space for other conditions or it could be invested back in the tertiary services budget given the current year on year decreases in the health budget, nationally and provincially. The cost-saving to the economy, which we did not include but should be mentioned, are also likely to be significant through preventing disability and loss of life which influences household financial stability and wellbeing.

Equally important is the feedback from patients, who found the intervention to be profoundly moving. The notion that one's provider cares so much that they're willing to call you when it's convenient for you, was in many cases the push our participants needed to take action for their health. As one participant put it: "If you're willing to help me", he says, "then I'm willing to help myself." Later, Mr K said, "If nobody is ever worried about you, or what you're up to, then you also don't worry." Mr K.

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Background

The PRO-Active TElemedicine TaCTical OpeRation (PROTECTOR) programme was a telehealth pilot intervention to support people living with poorly controlled diabetes. The aim of the intervention was to ascertain whether a short telehealth-delivered intervention could help patients to improve their diabetes control and self-efficacy and bring their measures (such as HbA1c) closer to clinically normal ranges. The objectives and measures are shown in Table 1.

Table 1: Objectives and measures

Question	Measure
Do **patient outcomes** improve, decline, or remain the same when a telehealth solution is implemented?	- HbA1c - Patient-reported outcomes (PROs) - Patient-reported self-efficacy (qualitative interviews)
How do **clients experience** the value of a telehealth service? Why and how might it work for clients?	- Qualitative interviews - Patient-reported experiences (PREs)
How **affordable** is a telehealth service?	Economic evaluation

Methods

Participant selection

Patients were selected using the Western Department of Health and Wellness' (WCDoHW) Single Patient Viewer (SPV) system according to the criteria in Table 2. A total of **423 patients** making use of Hanover Park Community Health Centre (CHC) were identified as meeting these criteria. However, the final number of participants in the PROTECTOR pilot was **91**, due to contactability and willingness to participate.

Table 2: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
- Known Diabetic – as per Provincial Health Data Centre (PHDC) algorithm. - Age >18 - Last HbA1c >10 - Last HbA1c date (01-11-2019 to 30-10-2021) - Last diabetic drug issued between 01-11-2020 to 30-10-2021	- Newly diagnosed patients - Pregnant patients (at any stage of intervention) - Type 1 Diabetics - Women with gestational diabetics

Inclusion criteria	Exclusion criteria
• Diabetic treatment start date between 01-01-2010 to 01-01-2019 • Last Activity Date between 01-01-2021 to 30-10-2021 • Last Diabetic Drug Issue at Hanover Park CHC	

The intervention

Figure 1 is an illustration of the PROTECTOR pilot patient journey, from introduction, through the intensive and maintenance phases, and finally exit or graduation from the programme. Patients from the SPV list were phoned by a telehealth surveyor who conducted the patients' baseline and endline surveys. In the baseline call, they were informed about the study and asked if they would like to participate.

If they agreed, the telehealth surveyor obtained consent and collected their demographic and socio-economic data via a Google™ form.

On completion, the patient was assigned a treatment cohort and informed of the date they would initiate on the programme.

Figure 1: PROTECTOR intervention
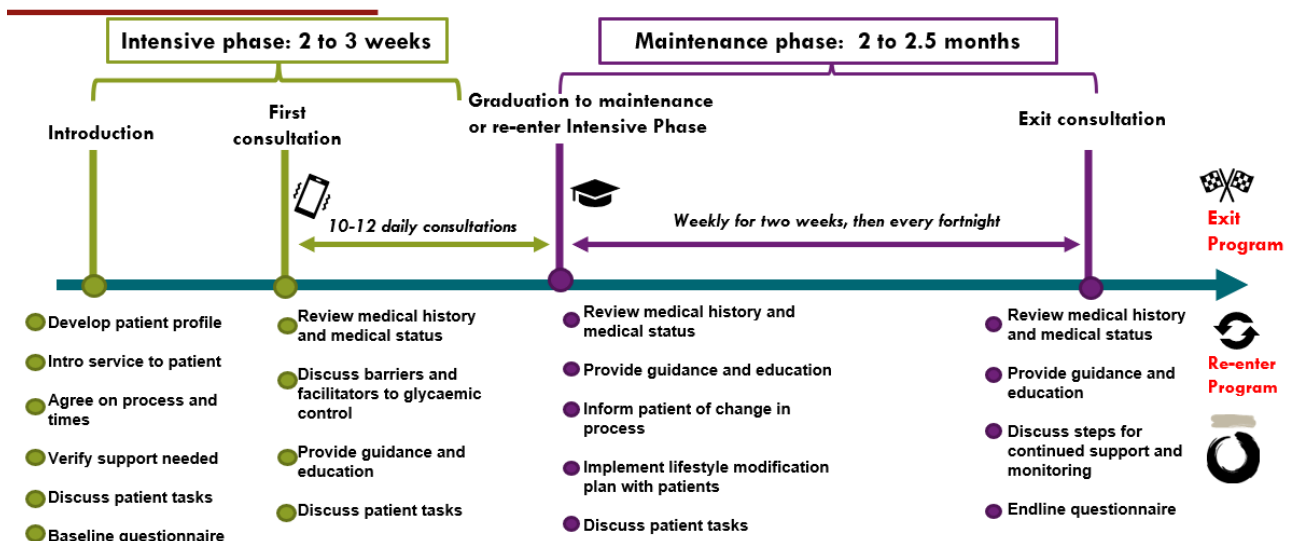
Intensive phase

On initiation, the patient was called by the telehealth doctor where she asked several clinical questions such as: (1) how long the patient has been living with diabetes, (2) what medications and dosages they are taking, (3) whether the patient has a glucometer home[1] (see Appendix 1). The telehealth doctor then called the patient every working day (Monday- Friday, excluding public holidays) for two weeks to check on their progress, obtain their blood glucose readings if they had a glucometer at home, and provide guidance on how to manage their blood sugar levels, as well as some advice on diet and behaviour. In total, all patients were offered 10 telephonic consultations during the intensive period with the telehealth doctor. If the telehealth doctor felt that a patient required more support or were not making sufficient clinical progress, she extended the intensive phase for a maximum of two additional consultations with the patient.

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[1] If the patient did not have a glucometer at home, the telehealth doctor liaised with Hanover Park CHC to provide the patient with one

Where patients were uncontactable/unreachable, the telehealth doctor would do her best to reschedule at a convenient time for the patient or determine whether the intensive phase period needed to be extended. As one can see from the data later in this report, most patients received less than the 10 available consultations. Patients who were not ready to enter maintenance phase after 12 consultations underwent a second intensive phase but were subsequently excluded from the results as their "dosage" differed from other patients.

Maintenance phase

This phase lasted eight to 10 weeks.

1. The maintenance phase lasted 8-10 weeks and the telehealth doctor called patients once per week for the first two weeks to check on their glucose control and provide further education and support (see Appendix 2).
2. After two weeks, the telehealth doctor called the patient fortnightly with the same aim.

Exit

Once the maintenance phase was over, patients were graduated from the programme and referred to Hanover Park CHC to have their exit HbA1c measures taken (entry HBA1Cs were derived from SPV as selection criteria). The telehealth doctor arranged the visit, by booking the patient on a specific date and time, to avoid long waiting times. The telehealth doctor also sent the patients' file numbers to Hanover Park CHC ahead of the visit so that the files were ready upon their arrival and the sample collection process was as efficient as possible.

After the HbA1c blood tests were done, the telehealth surveyor called the patient for an endline survey to find out about their experience of the intervention, and the perceived benefits or drawbacks (see Appendix 3).

Post-exit data collection

To gain insight into the experience of the pilot, we also interviewed some of the participants as well as the telehealth doctor and the medical doctor at Hanover Park CHC (who was also the co- designer of the pilot alongside Percept) for their health systems-related reflections.

Table 3 describes the available data for analysis that are used in the results section.

Table 3: Data points for analysis

Data point	Associated phase of research	Type of data	Collected by
Baseline demographic and socio-economic data and PROs & PREs	On entry	Quantitative	Telehealth surveyor
Clinical questionnaire (Appendix 1)	On initiation on intensive phase	Quantitative	Telehealth doctor
Blood glucose readings	Every day of intensive phase	Quantitative	Telehealth doctor
Survey data (Appendix 2)	Maintenance phase	Quantitative	Telehealth doctor
Blood glucose reading	Post intervention	Quantitative	Hanover Park CHC staff
Endline economic data, PROs & PREs and patient feedback (Appendix 3)	Post intervention	Quantitative	Telehealth surveyor
In-depth interviews	Post intervention	Qualitative	Percept

Results

PROTECTOR was measured using the following outcomes:

- Process measures
- Clinical outcomes as per best practice norms
- Patient-reported outcomes and patient-reported experience as designed for the intervention
- Qualitative interview findings
- Economic evaluation (of the pilot and the intervention at scale)

Descriptive statistics

Although 91 patients were enrolled in the pilot, this analysis was carried out on only 82 patients because:

- Two patients did not meet inclusion criteria and so were incorrectly enrolled.
- Three patients were excluded because they did not complete the program.
- Three patients were excluded because they did the intensive phase twice.
- One patient passed away before the intervention was completed.

The patients were split into four cohorts, to ensure the telehealth doctor had sufficient time for each patient. The first cohort had an older mean age of 62.3 years, and the mean age for the total study population was 58.0 years (Table 4). There were many more women (69%) than men (31%) in the study population.

Table 4: Demographic data

Descriptive	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
Sex	n (%)				
Female	16 (89%)	11 (58%)	15 (65%)	15 (68%)	57 (70%)
Male	2 (11%)	8 (42%)	8 (35%)	7 (22%)	25 (30%)
Age	n (%)				
<60	8 (44%)	11 (61%)	16 (70%)	11 (50%)	47 (57%)
>= 60	10 (56%)	7 (39%)	7 (30%)	11 (50%)	35 (43%)
Mean	62.3 [41;81]	59.1 [32;82]	54.3 [36;70]	57.4 [35;75]	58.0 [32;82]

Table 5 shows the different types of diabetes-related medication the PROTECTOR participants were on as well as the other most prominent co-morbidities. On average, PROTECTOR participants were on 2 different diabetes medications. This excludes the medication burden for other comorbid conditions, for which most participants had at least one.

Table 5: Medication use, comorbidities, and average duration of diabetes diagnosis

Medical Information	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
Total number of patients	18	19	23	22	**82**
Medication	n (%)				
Biphasic Insulin	14 (78%)	10 (53%)	13 (57%)	7 (32%)	44 (54%)
Basal Insulin	2 (11%)	5 (26%)	4 (17%)	7 (32%)	18 (22%)
Metformin	14 (78%)	18 (95%)	22 (96%)	18 (82%)	72 (88%)
Glimepiride	4 (22%)	6 (32%)	7 (30%)	10 (45%)	27 (33%)

Medical Information	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
ACE Inhibitor	11 (61%)	11 (58%)	13 (57%)	6 (27%)	41 (50%)
Statin	17 (94%)	16 (84%)	15 (65%)	17 (77%)	65 (79%)
Average number of diabetes medications	1.9	2.1	2.0	1.9	**2.0**
Comorbidities	**Individuals**				
Hypertension	17	15	20	20	72 (88%)
Hyperlipidaemia	15	15	15	17	62 (76%)
Chronic Kidney Disease	4	4	2	3	13 (16%)
Other	0	4	4	0	80 (10%)
Duration of diabetes	**Mean years [min;max]**				
Mean	7.4 [3.8;11.2]	8.0 [3.9;10.2]	7.8 [4.5;11.8]	8.2 [3.7;12.6]	7.7 [3.8;11.2]

Table 6 shows the average number of consults, per cohort and total, for each phase of the intervention and the number of people who had their medication altered during the pilot to optimise their diabetic treatment. It should be noted that all participants were already on some form of diabetes medication at the start of the pilot, and therefore the focus was on altering medication. The mean number of consultations during the intensive phase was 9.4, slightly under the expected number of 10. The majority (73%) of patients had their medication altered during the intervention to try optimise their glycaemic control.

Table 6: Number of consultations over the intervention

Intervention Information	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
Average number of consults	**Mean consults [min; max]**				
Daily consults (intensive)	10.8 [8; 12]	10.0 [5;12]	9.2 [6; 12]	7.8 [3; 11]	9.4 [3;12]
Maintenance consults (maintenance)	10.7 [7; 12]	11.0 [8;12]	9.6 [6; 12]	10.1 [6; 12]	10.3 [6;12]
Medication	**n (%)**				
Medication altered	15 (83%)	12 (63%)	15 (65%)	18 (82%)	60 (74%)
Medication not altered	3 (17%)	7 (37%)	8 (35%)	4 (18%)	22 (26%)

Process measures

We used several process measures to help us understand why the HbA1c levels increased/decreased after the PROTECTOR intervention:

a) Data relating to the number of calls made to the patient and the content of these calls (e.g., education on diet, or how to use a glucometer).

b) Data relating to what additional services were offered to the patient outside of the PROTECTOR clinical protocol, for example, medication changes and/or referrals to the Hannover Park CHC for in-person consultations.

Number of calls made and content of calls

The program was structured around 12 possible intensive, and 12 possible maintenance consultations. However not all consultations were considered necessary for all patients, so some patients were contacted less frequently, additionally, it wasn't always possible to contact patients. The distribution of successful intensive consultations

centred around 10 attempted consults, with the majority of patients having between five and 10 successful intensive consultations. The distribution of maintenance consults centred around eight attempted consults, with most patients having between five and 10 successful maintenance consults.

Figure 2 shows what percentage of consults were missed by patients. We see here that more than half of the PROTECTOR participants missed less than half their calls, and only 13 participants missed more than 33% of calls. This indicates that it was generally possible to reach the participants and correlates with the difference in attempted and successful appointments seen above.

Figure 2: Follow up calls missed

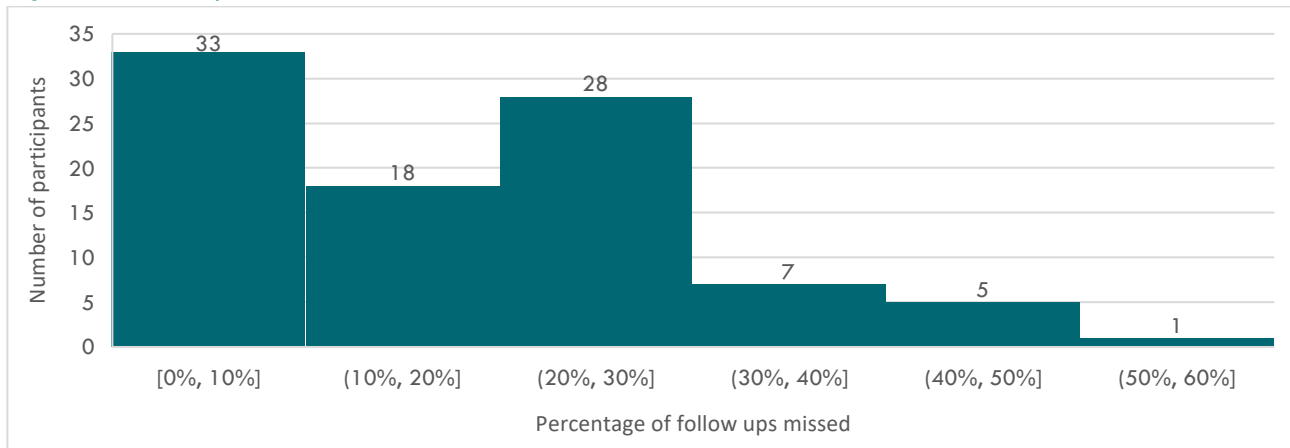Figure 3 and Figure 4 show that there was an educational component to most of both intensive and maintenance consults. During both the intensive and maintenance phases the key piece of education was on diet and meal planning as well as medication usage and adherence, with symptoms of hypoglycaemia and HGT levels and times to test being the second most common topics.

Figure 3: Education at Intensive consults
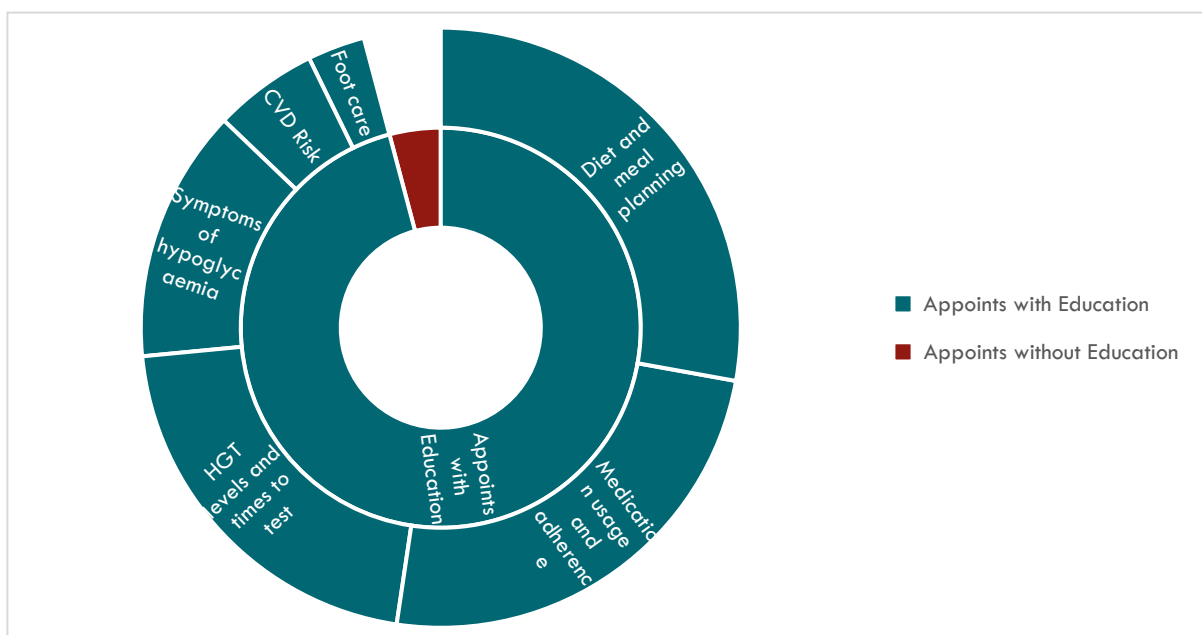
Figure 4: Education at Maintenance consults
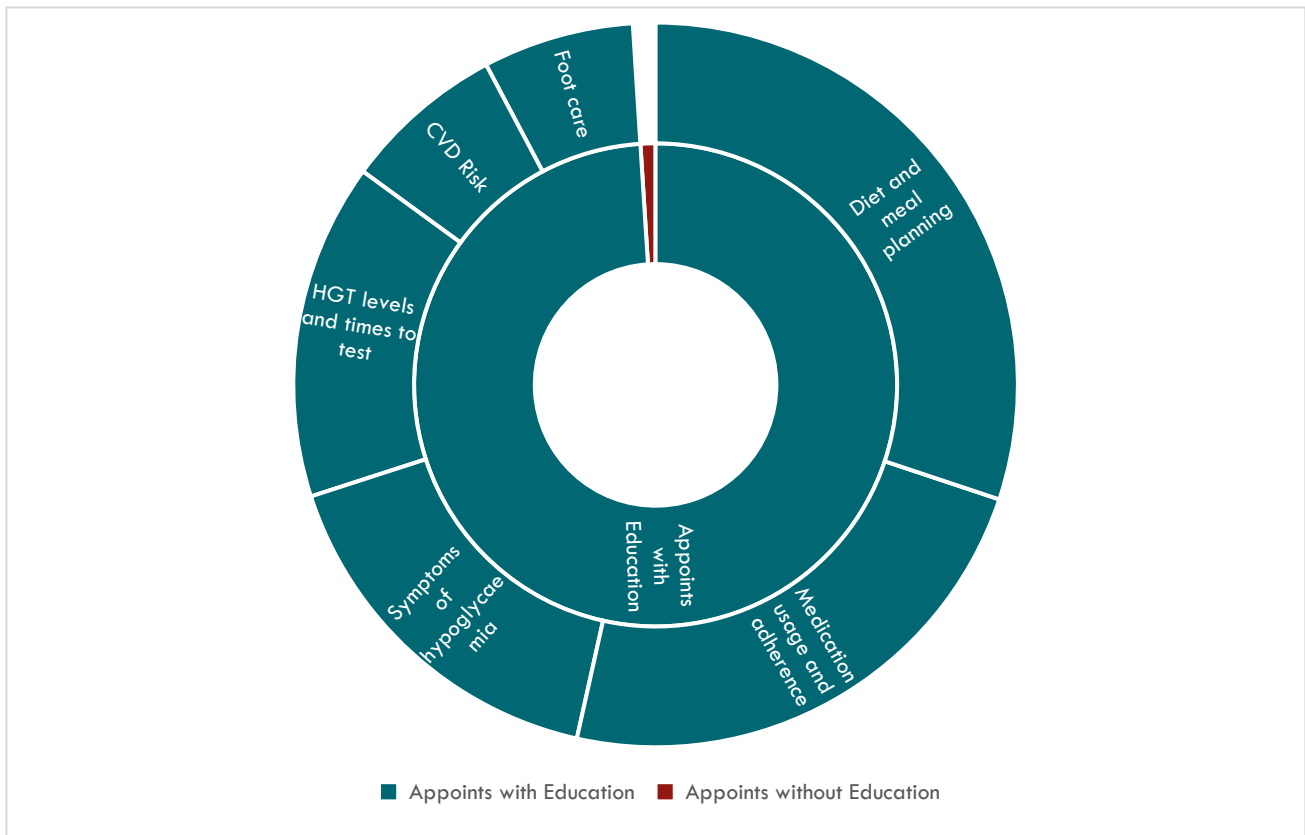
Additional treatment changes and referrals

Most patients (87%) were never referred to the clinic, and it was possible to manage their condition through the teleconsultation alone. This indicated that for the majority the management and support provided during consultations were sufficient and can be considered the main driver of outcome changes.

We also analysed how often consultations resulted in a patient's medications being altered. More than two-thirds of patients did have their medication changed during the pilot, with 41 patients having their medication changed more than once during the intervention. Therefore, medication management was a key part of the PROTECTOR pilot.

Clinical outcomes

HbA1c levels were used as the primary clinical outcome measure, where the hypothesis was that PROTECTOR would decrease HbA1c levels. Table 7 shows the mean pre- and post-intervention HbA1c levels. All cohorts show a decrease in HbA1c levels from before the intervention.

The average decrease in HbA1c levels is 2.9%, a remarkable result on its own, but this has been brought down by cohort 4's more muted results. The other three cohorts showed overall decreases of 4+ percentage points. Cohort 4 started with a lower average HbA1c, making it more difficult to lower (because you're close to the optimal measure) and they had slightly few intensive calls on average (7.8 as compared to an average of 10+ in the other three cohorts).

Table 7: Changes in HbA1c levels

HbA1c	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Total
HbA1c result	mean [min; max]				
Pre-intervention	14.2 [9; 16.6]	13.7 [10.7; 18.5]	14.2 [9; 16.6]	12.2 [10.5; 113.6]	13.2 [9; 18.5]
Post-intervention	10.0 [7.2; 14.6]	8.8 [7.1; 11.3]	10.0 [7.2; 14.6]	11.2 [8.6; 14.5]	10.2 [7.1; 15.2]
Change	4.2 [0.6; 9]	4.6 [1.2; 11.1]	4.2 [0.6; 9]	1.0 [-2; 4.6]	2.9 [-2; 11.1]

Figure 5 shows the numerical change in HbA1c levels by number of patients. Five patients (6%) had worsened HbA1c levels, while the majority of patients had an improvement between 0.1 and 6 percentage points. For the five who had worsened levels, the reasons ranged from difficulty in substantially changing diet, reluctance to increase medication dosage and one who could not access a glucometer which meant the patient and doctor couldn't track their progress on a daily basis.

Figure 5: Changes in HbA1c levels
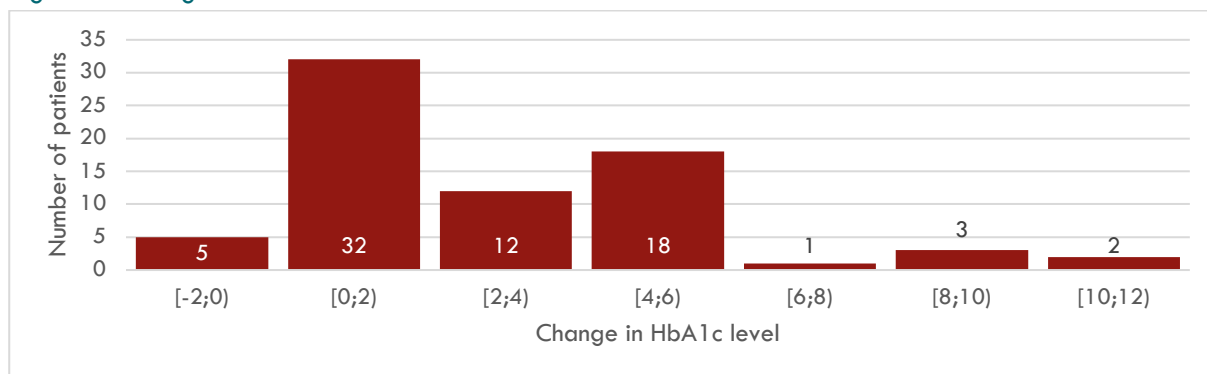
Patient-reported outcomes

Patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) were assessed using a 10-question survey which was administered at the start and end of the PROTECTOR protocol. All questions were answered by the patient by giving a score between 1-5, with one representing the most negative patient experience, and 5 representing the most positive patient experience. The exact questions, and the changes in the baseline and follow up mean answers, are shown in Table 8.

Table 8: PROMS and PREMS questions

PROM/PREM	Question	Baseline mean	Follow up mean	Improvement or decline?
PREM	1. People living with diabetes usually have to prepare or share food with other people who do not have diabetes (such as family members or friends). When this happens, how confident are you that you can follow your diet?	3.59	4.15	Improvement
PREM	2. People living with diabetes have to learn how to choose foods to eat when they are hungry, for example, snacks. When you are hungry, how confident are you that you can choose the appropriate food to eat?	3.54	4.29	Improvement

PROM/PREM	Question	Baseline mean	Follow up mean	Improvement or decline?
PREM	3. The blood sugar of people living with diabetes can go higher or lower than it should be. If your blood sugar levels goes lower of higher than it should be how confident are you that you know what to do?	4.32	4.71	Improvement
PREM	4. People living with diabetes have to learn which changes in their health they should see the doctor about. How confident are you that you know which changes in your health you should see the doctor about?	4.08	4.47	Improvement
PROM	5. Living with diabetes can interfere with the things you want to do. How confident are you that you can control your diabetes so it does not interfere with the things you want to do?	3.71	4.27	Improvement
PROM	6. For some people, living with diabetes is scary. When you think about living with diabetes, how scared do you feel?	3.24	3.41	Improvement
PROM	7. For some people, living with diabetes is depressing. When you think about living with diabetes, how depressed do you feel?	4.09	4.00	Decline
PROM	8. Living with diabetes takes physical and mental energy. For you, how draining do you find it to manage your diabetes?	3.01	3.12	Improvement
PROM	9. Some people living with diabetes worry about the future and the possibility of serious complications. How much do you worry about the future and the possibility of serious complications?	3.07	3.36	Improvement
PROM	10. Diabetes can cause complications. For you, how much of a problem is coping with the complications of diabetes?	2.99	3.30	Improvement

Table 8 shows that there were minor improvements in all patient-reported measures except for one, which showed a slight worsening (question seven regarding how depressed patients feel). To calculate the mean change across the pilot, the difference between a patient's baseline and follow-up score was calculated. Then the number of patients with each difference in score was counted, and the frequencies were plotted in a graph. The changes for each question are normally distributed with a centre around 0, indicating that most questions experienced no change. As already shown by the change in the means in Table 8, the results were slightly skewed, indicating that more patients reported their experience improving, rather than declining. Given how

entrenched people's behaviours are, and the fact that patient's home life was not changed through the pilot, even small positive changes in outcome measures are a very heartening sign of improvement. Unfortunately, the number of patients in the pilot was too small to assess whether there was statistical significance to the improvement.

Qualitative findings

The team conducted in-depth interviews with Dr Neal David and Dr Nafisa Khan, the co-designer of PROTECTOR and the telehealth doctor, respectively. We also interviewed the surveyor for PROTECTOR (Marche-Lerice Adams), who did the initial call, baseline and endline surveys with patients. We then interviewed two patients: "Mrs T" and "Mr K" (pseudonyms). These interviews helped us to develop a qualitative picture to further understand the process and outcome measures discussed above, as well as the provider experience. We have created vignettes for each of these interviews which will be circulated in separate documentation. Below we include part of one of the vignettes, developed from our interview with Mrs T.

Vignette: Mrs T

It has been more than 10 years since Mrs T [pseudonym], now a grandmother in her fifties, was first diagnosed with diabetes. Mrs T is enrolled at Hanover Park CHC (HPCHC), where she receives her insulin prescription, along with treatment for co-morbid hypertension and high cholesterol. In learning to accept, manage and live with diabetes over the past decade, Mrs T has had both important victories and serious challenges. She has become attuned to her body's signals, developed a morning medication routine, and accepted that she will need to manage her chronic conditions for the rest of her life. But she has also had to contend with a chain of stressful life events, including divorce and retrenchments. When faced with family and financial pressure, she has often found it more difficult to stay well.

In 2021, as part of PROTECTOR, Mrs T received an introductory phone call from Dr Khan. *"They'd picked up at HPCHC that my sugar [levels] were [like] a bouncing ball [going] up and down."* Mrs T says that, at the time, she was trying to eat well and stick to her medication but was still struggling to keep her sugar levels under control and welcomed the assistance from Dr Khan.

"I thought, it can only be my stresses, because I was unemployed [...] So, if someone can help me regulate this thing, I mean, why not? And then we [Dr Khan and I] just started. I think I liked it when somebody was there."

Dr Khan would check in regularly with Mrs T telephonically and via WhatsApp, and Mrs T would text her daily glucometer readings to Dr Khan. *"If she didn't phone, we chatted,"* Mrs T explains. *"I liked that, because it showed me, she cared about how I'm feeling, how I'm doing. And I mean, you don't really get that at the HPCHC."* Being in regular contact with Dr Khan motivated Mrs T to track her glucometer readings. And in turn, seeing good readings, offered positive reinforcement of the changes she was making. *"Before I started with Dr Khan, I never used my machine, never. It gathered dust, really, laying in my drawer [...]"* Mrs T explains. *"Before, [even though] I used to take the medication every day, I was never interested to see what my sugar reading actually was. And when I started doing this, I thought, this [reading] is not bad. I like the way my sugar is looking!"*

Mrs T says that she and Dr Khan were able to chat 'like friends,' not like 'doctor-patient,' which was another contrast to her experience of in-person primary healthcare. *"When you're at the hospital,"* she explains, *"they [the healthcare workers] will let you know, 'Listen here, I'm in charge, so you need to do as I say.' Dr Khan didn't do that. Maybe that's why we communicated so well."* While Mrs T celebrated being able to consult Dr Khan without long hours of queueing; her reflections on the telehealth intervention focused more-often on a level of attentiveness and care that is rarely afforded in overburdened public health facilities. When asked whether she thought other diabetic patients might benefit from telehealth, Mrs T said: *"I think that is a very good idea. Sometimes people don't like to talk at hospitals because there are a lot of people waiting to be seen by the doctor, the nurse, or whoever… So, when you go in there, you only have so many minutes, because the hospital is so full and because when you're done there, you still need to go sit in the queue by the chemist. I feel better chatting to Dr Khan about something. Yeah, I would never do that [have those conversations] at the hospital because there's no time. The people there, they don't have patience for you [...] So, this initiative works. I think it works very well."*

From these interviews, several themes were elicited. The strongest theme was that patients felt their healthcare provider cared equally as much about their health status and wellbeing as they did. This feeling of being cared for helped patients to stay on the programme and remain motivated.

Figure 6: Reciprocity and relationships

> "If you're willing to help me", he says, "then I'm willing to help myself." Later, Mr K said, "If nobody is ever worried about you, or what you're up to, then you also don't worry." Mr K

> "I was actually pleasantly surprised that you could in actual fact build a relationship with the patient and actually improve their management telephonically" Dr Khan

> "Both of them have been extremely appreciative of somebody being interested in their care. […] they were so shocked that somebody from the Western Cape government is actually phoning them and actually calling them to find out how they're feeling. For them, that was like amazing. I mean, they couldn't stop complimenting government and what they were doing for them. So, I think it was the same thing that came through here, they couldn't believe that Hanover Park was actually making somebody call them to find out how they're doing." Dr Khan

> "You know, even though it's been months since I spoke to a patient, many of them, you can literally hear the difference in the voice. When they do speak with you. It feels like the weight, literally, a weight has been lifted off them. And, you know, It's so heartwarming, it's so encouraging. Just to hear that patient when they answer the phone and say, 'Hi, Mrs. How are you?' And I mean, if I start off the same way as I did before we started, and il'd say, 'Hi, good morning, how are you? Many of them are ar like, 'What do you want? I'm okay, I'm fine.' And before I even say that it's me, immediately, you can here 'No, I'm fine. How are you?' And then I say 'no, thank you. I'm doing good. I'm doing well.' And then I would say, 'It's Marche from Percept.' And they say, 'Oh, yes'. And I say 'Do you remember me?' And you know, you can hear in the voice the difference. Literally, like this heaviness, lifted off them." Marche

Economic evaluation

The team also conducted a costing to determine the overall economic and financial cost of the PROTECTOR pilot as well as the cost if PROTECTOR if it were to be scaled at a district and provincial level. This costing is an important part of assessing impact for a new intervention as it gives a sense as to whether (1) the outlay costs are feasible for the Western Cape Department of Health of Wellness (WCDoHW) (2) there are any savings to the system (within one financial year) that can be used to fund the programme's operational costs.

Economic costs relate mostly to pilots, and it includes all activities even if they weren't directly funded (for example, developing the PROTECTOR intervention). This ensures that the true cost of a new intervention is considered. Financial costs include only that which was paid for directly, and so it is by nature always less than the economic cost. The PROTECTOR pilot was funded by the Bill & Melinda Gates Foundation, through Percept's Primary Health Care Innovation grant. Therefore, while the economic cost is important to make visible, this costing focuses on the financial cost as this is the cost WCDoHW needs to consider with regards to scale up.

Cost of the pilot

First, we calculated the financial and economic cost of running the PROTECTOR pilot. As mentioned, the pilot was doctor-led with one telehealth doctor calling all the patients. She was supported by HPCHC for clinical-related issues and the Percept team took responsibility for managing the enrolment of each cohort, paid for the telehealth doctor and surveyor and conducted the analysis of the outcomes.

Table 9 shows that the pilot's total economic cost was ~R1.35 million, and its financial cost was slightly lower at ~R1.27 million. This was the cost of recruiting the original 92 patients, of which the final number of participants was 82, as described earlier in this report. This therefore translated to a per patient economic and financial cost (for the 82 who completed) of R16,415 and R15,477 respectively. The average cost per phone call made was therefore R821 (economic cost) or R772 (financial cost), using an average of 20 calls per patients.

Table 9: Economic and financial costs of PROTECTOR pilot

Cost category	Economic cost (R)	Financial cost (R)
Start-up costs		
Intervention Design	128 001	105 951
Recruitment	1 676	1 053
Training	10 672	2 247
Total start-up costs	**140 350**	**109 251**
Operational costs		

Cost category	Economic cost (R)	Financial cost (R)
Recurrent	**1 197 211**	**1 157 138**
Personnel	*1 154 337*	*1 147 850*
Other recurrent costs	*42 874*	*9 288*
Capital	**8 510**	**251**
Total operational costs	**1 205 721**	**1 157 389**
Total	**1 346 071**	**1 266 640**
Cost per patient	*15 124*	*14 232*
Cost per call	*R821*	*R772*

To determine the cost of PROTECTOR at a district and provincial scale, the team then needed to determine the number of patients that needed the intervention. The team first looked at the Klipfontein Health Sub-District (KHSD), in which HPCHC falls, and reviewed all patients who met the eligibility criteria for PROTECTOR, as well as people living with HIV and TB whose clinical outcomes were sub-optimal. We then assumed that only 30% of these could be reached due to difficulties in cellphone number accuracy in the health system. It could be even less than 30% who are reachable, given the experience with other tele-interventions however given that this intervention focuses on very high-risk clients. However, it's likely many of them are known to the health system and frequent attenders given their risk for complications. The final number of clients who would benefit from an intervention like PROTECTOR per year (adapted for the specific disease pathway) in the KHS district was 4,565 (Table 10). It is important to note that this is an annual number and we expect the number to remain stable (or even increase) as PROTETCOR will support greater access to healthcare services, allowing the health system to better care for those already in the system (demand) and well as those who are not yet in the system, but should be (unmet need).

Table 10: Determining number of patients for expanded PROTECTOR in KHSD

KHSD demographics	Data (per annum)
Total uninsured population	430,000
Estimated target population (uncontrolled T2DM, HIV and TB)	15,215
% target	4%
Contactable/reachable clients for VC	30%
Number of clients who would benefit from intervention each year	**4,565**

After engagement with Dr Neal David, the idea of a 'virtual clinic' was used, moulded from the VECTOR project during COVID, to understand the staffing costs required to support this number of patients. A virtual clinic would need two medical officers, linkage to community health workers and other support staff, composed of:

- "Facility" Manager
- 1 Operational Manager Nursing Grade 1 (General Unit)
- 1 Administrative officer
- Referral pathways for additional clinical support: social workers, occupational therapists and other allied health professionals
- Referral pathways into the provincial call centre for non-clinical support and follow up
- 2 telehealth Case Manager (registered nurse) Professional Nurse Grade 2

This virtual clinic would be able to support 4,656 patients on the intervention per annum, after which patients who 'graduate' could be handed over to the provincial call centre for quarterly or bi-annual telephonic check-ins, unless they would need re-intervention on referral. This would also ensure that PROTECTOR remains plugged

into the 'traditional' health system and patients remain supported telephonically even after the intervention has completed. Call centre agents can be trained to know when a patient needs to be referred back into a facility for further clinical management.

The team then did the same exercise of determining eligible patients but for the entire Western Cape (WC) Province. The total eligible patients were determined as 47,745 for the province. The 30% reachable rate was then overlayed to arrive at a total of 14,324 patients eligible for the expanded PROTECTOR intervention across the country. Given that each virtual clinic can see 4,565 patients, we then divided 14,324 by 4,565 to arrive at a need for three (3) virtual clinics for the WC.

This virtual clinic was costed at scale in Klipfontein (1 clinic) and provincially (3 clinics), and the cost per patient comes down to R1,139 (from R15,447) given the economies of scale of a fuller team who can look after a larger cohort (Table 11). The cost per telephonic consult also comes down substantially from R772 to R57 per telephone call.

Table 11: Financial cost at scale in the district and province

Cost category	Financial cost- Klipfontein Health Sub-District reachable, target population	Estimated cost: Province-wide reachable target population
Start-up costs		
Training	R10 672	R33 489
Recurrent operational costs		
Personnel	R4 486 119	R14 077 588
Other recurrent costs	R529 644	R1 662 040
Capital operational costs		
Capital costs	R172 700	R541 939
Total per annum	**R5 199 135**	**R16 315 056**
Number of reachable target population	4 565	14 324
Cost per patient	**R1 139**	**R1 139**
Cost per telephonic consult	**R57**	**R57**

Calculating savings

Given that this intervention will require additional funding to get started, we also looked at the potential savings the WCDoHW could accrue by funding this intervention. Table 12 is a reminder of the median change in HbA1c levels, where the total across all four cohorts was a 2.66 percentage point change from baseline to endline HbA1c reading.

Table 12: Median change in HbA1c levels for PROTECTOR participants

	Number of participants	Mean age	Median % change
Total	**82**	**58.0**	**2.66**
Cohort 1 participants	18	62.3	3.55
Cohort 2 participants	19	59.1	5
Cohort 3 participants	23	54.3	1.4
Cohort 4 participants	22	57.4	0.7

To calculate the savings, we looked at two scenarios. Table 14 shows a summarised version of each scenario. All data is reported on a per annum basis. In scenario 1, we used a South Africa-based research paper by Erzse et al (2019). In this paper, the authors estimate a 15% risk rate for complications for patients with uncontrolled diabetes. The average cost per complication was estimated at R37,127. So to arrive at the estimated total saving, one multiplies the PROTETCOR participants by 15% and then multiplies those 15% of people by R37,127 to arrive at a total savings (due to complications averted).

In scenario two, we use Erzse et al (2019) paper again for their estimated cost of a myocardial infarction (MI)- R187,296. We then used a paper by Lind et al (2021) which provided evidence on how the risk of an MI is lowered with every percentage point a patient's HbA1c is lowered, for those who have just been diagnosed with T2DM (19.7%) and those who have had their diagnoses for 10+ years. Given that the PROTECTOR pilot clients had all been living with their T2DM for more than eight years, we went with the 6.50% reduction in MI risk for everyone one percentage point the HbA1c reading is lowered by. Given that the PROTECTOR intervention showed an average reduction of 2.66%, the reduction in MI risk complication is 6.50%*2.66 which is 17%. Lastly, we needed an assumption for who was at risk of an MI. We used Ciu et al (2021) paper which shows a 30% risk for MI in people with uncontrolled T2DM. Table 13 shows the actual number of averted complications when PROTECTOR is rolled out at sale at the district and province level. Table 14 details the data for each scenario described above.

Table 13: Number of averted complications per annum

Number of averted complications	KHSD	Province-wide
Averted complications per annum (all)	538	2,127
Averted MIs per annum only	237	744

Table 14: Scenario details

Assumption	Value	Source
Scenario One		
Percentage of uncontrolled T2DM patients who complicate	15%	Agnes Erzse, Nicholas Stacey, Lumbwe Chola, Aviva Tugendhaft, Melvyn Freeman & Karen Hofman (2019) The direct medical cost of type 2 diabetes mellitus in South Africa: a cost of illness study, Global Health Action
Spend per patient with complications	R37,127	
Scenario Two		
Cost of an MI complication	R187,296	Agnes Erzse, Nicholas Stacey, Lumbwe Chola, Aviva Tugendhaft, Melvyn Freeman & Karen Hofman (2019) The direct medical cost of type 2 diabetes mellitus in South Africa: a cost of illness study, Global Health Action
If HbA1c lowered by 1% at diagnosis, reduction in myocardial infarction (MI) complication risk	19.70%	Marcus Lind, Imberg, H., Coleman, RL., Nerman, O., Holman, R. Historical HbA1c Values May Explain the Type 2 Diabetes Legacy Effect: UKPDS 88. Diabetes Care 2021
If HbA1c lowered by 1% 10+ years post diagnosis, reduction in MI complication risk	6.50%	The mean duration since diagnosis of PROTECTOR patients was 8.2years, so these were known T2DM clients
Reduction in MI complication risk for PROTECTOR participants	17%	

Assumption	Value	Source
MI Risk in diabetics assuming mix of those with MI history and those without	30%	Cui J, Liu Y, Li Y, Xu F, Liu Y. Type 2 Diabetes and Myocardial Infarction: Recent Clinical Evidence and Perspective. Front Cardiovasc Med. 2021 Feb

Table 15 shows the savings per scenario, in the pilot, at scale in KHSD and at scale for the whole province. The savings are substantial, **with a return on investment between 284%-754%.**

Table 15: Savings and return on investment

	Pilot	At scale in KHSD	At scale across Western Cape Province
PROTECTOR intervention costs	R1,266,640	R5,199,135	R 16,315,056
Scenario 1 savings to health system	-R814,615	R19,962,671	R62,643,512
Scenario 2 savings to health system	R797,382	R 44,385,993	R139,284,693
Savings/cost: Scenario 1	-0.64	3.84	3.84
Savings/cost: Scenario 2	0.63	8.54	8.54
Rand saving per Rand spent Scenario 1	-R0.64	R3.84	R3.84
Rand saving per Rand spent Scenario 2	R0.63	R8.54	R8.54
Return on investment		284%-754%	

Reflections and lessons

Health system

Clear and seamless referral pathways. The telehealth project, whilst functioning remotely from HPCHC, was still integrated into the CHC's service delivery processes. The telehealth doctor had access to the clinical and administrative staff at the facility and was therefore able to facilitate processes, such as referrals to the facility and changes to medication. The telehealth doctor was also able to draw on the facility for certain tasks, such as confirming patient contact details or repeating blood tests. This was because she was already known to te facility and its staff. This relationship building between telehealth doctor and referral clinic/CHC is therefore an important factor for a successful referral pathway.

Streamlining the patient journey. One of the major benefits of this programme for patients was facilitating their diabetes journey and resolving barriers to adherence, so that their experience at the facility was fast and positive. For instance, the telehealth doctor was able to assist patients with obtaining glucometers when they needed them by being in direct contact with the HPCHC pharmacist; she was able to update patients' medication dosages and communicate this to the facility to make notes of these changes in the patients' files; and she was able to facilitate the patient being able to book their appointment (rather than join the general walk-in queue on the day).

Digitising and integrating health information systems is crucial. This integration with the HPCHC has strengthened the programme by ensuring that there is continuity with the patients' treatment. However, there is still room for improvement to ensure that telehealth programmes can function seamlessly within the larger health system. Firstly, since there is no complete Electronic Health Record (EHR) for patients, the telehealth doctor and the health facility need to triangulate patient information between Dr Khan's telehealth consultation notes, SPV, and patients' physical files which are stored at HPCHC – and these data sources are sometimes conflicting. This telehealth programme has shown that integrated digital Health Information Systems (HIS) are essential to both the efficient management of patients and efficient utilisation of health systems resources. This integrated digital HIS should include tools such as e-scripting, integrated and interoperable electronic clinical records, electronic appointment and referral systems, and the linkage of community health workers with telehealth teams.

Patient

Socioeconomic factors impact programme delivery. Although patients were very receptive and appreciative of the programme, certain social and economic barriers posed a challenge to its delivery. These include lack of reliable contact details, limited or shared access to cell phones, lack of airtime and data, language barriers, and difficulty with answering calls during working hours. In addition to this, despite high patient motivation and engagement, social factors hampered some patients' ability to change their lifestyle, such as poverty and food insecurity, crime and gang violence near the health facility or their neighbourhood, and family and other social stressors. A successful telehealth intervention therefore needs to cater to the patient's needs in terms of access to the intervention itself as well as access to social support structures, including referrals to allied health professionals.

Identifying patients with disabilities. Among the first cohort, patients with hearing, visual, and mental impairments and disabilities were identified. These patients required the support of family members and neighbours to take their blood glucose readings and/or speak to Dr Khan on their behalf. This highlights several learnings:

1. Telehealth is an effective way of identifying diabetics whose HbA1c is above optimal levels because of impairments or disabilities which make them unable to attend health facilities and/or look after themselves.
2. A telehealth doctor is able to include the patients' families in their care and educate their caregivers on what blood sugar readings are considered healthy, and what diet and behavioural changes are needed to maintain healthy blood sugar.
3. Identifying high risk diabetics that need additional support, creates the potential for mobilising community health workers to assist these patients.

Appendix 1: Intensive phase data collection

Initial consult with telehealth doctor

Activity	Key Processes/Outcomes
Review current medical history and clinical status	Acute Complaints Comorbidities Note and remind of dates of last and upcoming screening for retinopathy screening, foot ulcers, renal function tests etc Review medication for correct type and dosage Review testing materials (glucometer and strips) and ability to use them
Discuss barriers and facilitators to achieving glycaemic control with patient	Biological - side effects, co-morbidities, complicated medication regimens Psychological - mental load of condition, anxiety, stress, depression Behavioural - diet, exercise, smoking, alcohol and drug use Social - access to food, support structures
Provide guidance and education	Cardiovascular Disease (CVD) Risk Foot care Diet and meal planning Adherence Symptoms of hypoglycaemia Medication usage
Patient Tasks (if any)	

Daily consultation

Activity	Key Processes/Outcomes
Review current medical history and clinical status	Acute complaints Review personal health records Two-week log to help track patterns for change?
Provide guidance and education	CVD Risk Foot care Diet and meal planning Adherence Symptoms of hypoglycaemia Medication usage

Activity	Key Processes/Outcomes
Patient Tasks (if any)	

Final consultation to determine patient eligibility for maintenance phase

Activity	Key Processes/Outcomes
Review current medical history and clinical status	Acute complaints Review personal health records Two-week log to help track patterns for change
Provide guidance and education	CVD Risk Foot care Diet and meal planning Adherence Symptoms of hypoglycaemia Medication usage
Implement lifestyle modification plan with patient	Discuss plan for glycaemic control i.e., biological, psychological, behavioural and social interventions
Patient Tasks (if any)	

Breakdown of activities for Maintenance phase

Activity	Resources Needed	Key Processes/Outcomes
Review current medical history and clinical status	Access to SPV and patient files Patient diary (actual or picture) Access to resources such as: Social worker Psychologist Nutritionist Social resources such as exercise classes	Acute complaints Review personal health records Two-week log to help track patterns for change?
Provide guidance and education		CVD Risk Foot care Diet and meal planning Adherence Symptoms of hypoglycaemia Medication usage

Activity	Resources Needed	Key Processes/Outcomes
Patient Tasks (if any)		

Breakdown of activities for exit from the program

Activity	Resources Needed	Key Processes/Outcomes
Review current medical history and clinical status	Patient diary (actual or picture) Access to resources such as: Social worker Psychologist Nutritionist Social resources such as exercise classes	Acute complaints Review personal health records Two-week log to help track patterns for change?
Provide guidance and education		CVD Risk Foot care Diet and meal planning Adherence Symptoms of hypoglycaemia Medication usage
Discuss steps for continued support and monitoring		

Survey questions/data points
Date of Call
Time of Call
Length of Call (in minutes)
Unable To Contact
Next Appointment Date
Blood Sugar (mmol/l) - Fasting
Blood Sugar (mmol/l) - Before Supper
Blood Sugar (mmol/l) - 2 Hours Post Prandial
Acute Complaints
Specify Acute Complaints
Adjusted Medication
Specify Adjustments Made
Patient Education Given (Select All That Apply)

Survey questions/data points
Other Patient Education Given
Referral To Hanover Park
Reason for Referral to Hanover Park
Referred To Allied Services and Resources (Select All That Apply)
Other Referred to Allied Services and Resources
Patient Given Tasks
Specify Tasks Given
Worrying about the future and the possibility of serious complications on a scale of 0-4 (where 4 is
Clinician Comments

Appendix 2: Maintenance phase data collection questions

Data collection questions/point
Date of Call
Time of Call
Length of Call (in minutes)
Unable To Contact
Next Appointment Date
Blood Sugar (mmol/l) - Fasting
Blood Sugar (mmol/l) - Before Supper
Blood Sugar (mmol/l) - 2 Hours Post Prandial
Acute Complaints
Specify Acute Complaints
Behaviour Factors Log: Smoking
Behaviour Factors Log: Alcohol
Behaviour Factors Log: Diet
Behaviour Factors Log: Exercise
Adjusted Medication
Specify Adjustments Made
Patient Education Given (Select All That Apply)
Other Patient Education Given
Referral To Hanover Park
Reason for Referral to Hanover Park
Referred To Allied Services and Resources (Select All That Apply)
Other Referred to Allied Services and Resources
Lifestyle and Behavioural Risk Factors Plan Discussed
Specify Plan Discussed with Patient
Patient Given Tasks
Specify Tasks Given
Clinician Comments

Appendix 3: Endline survey

Follow up survey questions
a)   What is the gender assigned on your ID?
b)   If you responded other, please specify the gender with which you identify?
1. People living with diabetes usually have to prepare or share food with other people who do not have diabetes (such as family members or friends). When this happens, how confident are you that you can follow your diet?
2. People living with diabetes have to learn how to choose foods to eat when they are hungry, for example, snacks. When you are hungry, how confident are you that you can choose the appropriate food to eat?
3. The blood sugar of people living with diabetes can go higher or lower than it should be. If your blood sugar levels go lower of higher than it should be how confident are you that you know what to do?
4. People living with diabetes have to learn which changes in their health they should see the doctor about. How confident are you that you know which changes in your health you should see the doctor about?
5. Living with diabetes can interfere with the things you want to do. How confident are you that you can control your diabetes, so it does not interfere with the things you want to do?
6. For some people, living with diabetes is scary. When you think about living with diabetes, how scared do you feel?
7. For some people, living with diabetes is depressing. When you think about living with diabetes, how depressed do you feel?
8. Living with diabetes takes physical and mental energy. For you, how draining do you find it to manage your diabetes?
9. Some people living with diabetes worry about the future and the possibility of serious complications. How much do you worry about the future and the possibility of serious complications?
10. Diabetes can cause complications. For you, how much of a problem is coping with the complications of diabetes?
Before the telephone consultations with the telehealth doctor, did you attend the Hanover Park CHC?
What other facility did you attend?
10.How did you normally travel to the facility you attended? walked, taxi, bus, car, own transport, other
11. When you need to visit the Hanover Park facility, how much do you spend on TRANSPORT?
12. When you need to visit the Hanover Park facility, how much do you spend on FOOD?
13. When you need to visit the Hanover Park facility, how much do you spend on CHILDCARE?
14. Are there any OTHER expenses you incurred when visiting the health facility?
15. How much did you spend on these OTHER expenses?
16. How long would it take you to get to the facility?
17. When you got to the facility, how much time did you spend there? (including queuing and/or waiting for medication)
18. Did you ever miss work because you had to go to the facility?
19. Did you ever lose income because you had to go to the facility?
20. If you did lose income because you had to visit the health facility, how much did you lose per visit?
21. Does someone need to accompany you to the facility when you go?
22. If yes, who is the person who accompanies you to the facility?
23. If a paid carer/helper goes to the facility with you, how much do you pay this person?
24. Did the person who accompanied you to the facility need to miss work to come with you?
25. Have you ever been unable to attend the clinic when you needed to?
26. If you were unable to visit the facility when you needed to, what was the reason why? [select all that apply]

Follow up survey questions
27. Were you ever unable to collect your medication from the facility?
28. What was the reason you were unable to collect your medication? [select all that apply]
29. Were you unable to seek care or collect your medication because you were afraid of contracting COVID at the facility?
30. Did you ever seek diabetes care at a private facility? (i.e.: private GP, pharmacy, etc)
31. Why did you use the private facility? [select all that apply]
32. How much did you pay at the private facility for the consultation?
33. Did this payment include medication
34. How much did you pay at the private facility for the medication?
35. Have the telephone consultations with Dr Nafisa Khan benefitted you?
How have the calls with Dr. Nafisa Khan helped you? [Do not prompt respondent. Select all that apply]
Why do you feel the intervention has not benefited you? [Do not prompt respondent. Select all that apply]
If you were to have telephone consultations with your doctor in the future, would you prefer:
Have the calls with the doctor helped you to take your medication more consistently?
Have the calls with the doctor helped you understand how to monitor your glucose levels with the glucometer?
Is there anything you would like to add about your experience with the consultations with Dr. Nafisa Khan or the Hanover Park CHC?
Was this survey terminated early?
If yes, why?
Is there anything you would like us to be aware of regarding this call?