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# Pilot feasibility and efficacy of a strategy to sustain A1C improvement among diverse adults with type 2 diabetes completing a diabetes care management program

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## ABSTRACT

**Introduction** Evidence-based strategies are needed to sustain improvements in outcomes following diabetes care management (DCM) programs. We examined the impact of Boot Camp-Plus (BC-Plus), an innovative sustaining strategy, on A1C among adults with type 2 diabetes completing a 3-month Diabetes Boot Camp (DBC). This health system sponsored program consisted of diabetes self-management education and support, medical nutrition therapy and antihyperglycemic medications management.

**Research design and methods** From March 2019 to July 2021, adult DBC completers with Medicare or a health system Medicaid or employee commercial plan were enrolled in BC-Plus for 9 months. DBC completers not meeting insurance eligibility or who declined to participate in BC-Plus acted as controls. During the first 3 months, BC-Plus participants received ongoing daily remote blood glucose (BG) monitoring; and during all 9 months, they received monthly check-in calls with BG review by a medical assistant who addressed needs for supplies/drugs, whether participants were checking BGs, and self-care encouragement. Escalation to a nurse practitioner occurred if the monthly BG trend was >200 mg/dL and/or several BG <80 mg/dL and/or new A1C >9.0% were identified. A1C was followed for an additional 9 months post-BC-Plus. A longitudinal mixed effects analysis was used to assess change in A1C from month 0 to month 21 of follow-up between BC-Plus participants versus controls.

**Results** A total of 838 DCM completers were identified, among whom 281 joined the BC-Plus intervention and 557 acted as controls. Mean age was 55.9 years; 58.2% were women; 66.2% were black; and 30.6% insured by Medicare. BC-Plus participants experienced significantly lower A1C compared with controls and remained below 8.0% to month 18.

**Conclusions** Among completers of a 3-month DCM program, a low intensity 9-month sustaining strategy maintained A1C under 8.0% (HEDIS (Healthcare Effectiveness Data and Information Set) threshold

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Substantial evidence exists supporting the positive impact of diabetes care management (DCM) programs on glycemic control - for purposes of this report, DCM incorporates provision of diabetes self-management education and support (DSMES), medical nutrition therapy, and timely advancement of type 2 diabetes medications1.[1]

⇒ Subsequent, lighter touch interventions intended to sustain the glycemic control improvement achieved by an intensive DCM intervention are not well studied.

⇒ We examine the impact of Boot Camp-Plus (BC-Plus), an innovative 9-month 'sustaining strategy', on long-term glycemic control over 18 months after completion of a 3-month 'Diabetes Boot Camp' health system sponsored intensive DCM program.

### WHAT THIS STUDY ADDS

⇒ Sustaining strategy participants experienced significantly lower longer term A1C (<8.0%) compared with concurrent controls during the 9-month BC-Plus period plus an additional 6 months following its completion.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ In persons completing an initial intensive DCM program, a 9-month lighter touch sustaining strategy maintained A1C <8.0% to 6 months after follow-up program completion.

⇒ This evidence suggests that a lighter touch program may be leveraged to sustain A1C lowering resulting from an intensive DCM program.

⇒ Additional research into longer term sustaining strategies for completers of intensive DCM programs is needed.

for diabetes control) compared with controls for 15 months after completion of the initial DCM intervention.

## INTRODUCTION/BACKGROUND

Healthcare management may be defined as a team-based, patient-centered approach to assist individuals in optimally self-managing a chronic disease.[1] In this report, diabetes care management (DCM) will refer to care management interventions for people with diabetes that include provision of diabetes self-management education and support (DSME), medical nutrition therapy (MNT), and medication management provided by non-physician members of the care team under the supervision of a physician provider. The evidence demonstrating the impact of focused type 2 diabetes (T2D) care management strategies on glycemic outcomes is considerable. A body of evidence from clinical trials[1 2] and quality improvement initiatives[3 4] demonstrates the positive impact of DCM interventions among adults with T2D which incorporate a multidisciplinary team and/or anti-hyperglycemic medications management and/or DSMES on outcomes including hemoglobin A1C (A1C). A recent systematic review on strategies to overcome therapeutic inertia found that nurse-based or Certified Diabetes Care and Education Specialist (CDCES)-based interventions reduced A1C by −1.62% to −0.40% compared with controls.[1] This compares similarly to the −1.5% to −0.60% lowering in A1C seen with the initiation of common diabetes medications.[5] Typically, DCM programs are time-bound, with the expectation that after the program, the person with diabetes (PWD) will continue to self-manage their diabetes and sustain the benefits they received from the program. Most studies evaluating DCM intervention effectiveness have reported durations varying from 3 to 12 months.[3]

Evidence on the durability of outcomes after focused DCM interventions have been completed is lacking. Our local assessment of sustainability of glycemic control after completion of a 3-month, previously reported, intensive DCM intervention[6] found that gains in A1C began to wane within 3–6 months following program completion. By 6 months post-completion, 32% of participants experienced a greater than 1% increase in this metric; and at 12 months fully 45% had a greater than 1% increase.[7]

To our knowledge, there have not been reports of scaled down DCM 'sustaining strategies' intended to support the maintenance of the glycemic benefits accrued during a primary DCM intervention. One can make the case that outcomes seen with DCM programs are not beneficial to their full potential if they are not sustained over time. For example, if A1C lowering is not maintained, long-term reduction in risk for microvascular complications of T2D over time would be mitigated. Furthermore, expecting an intensive DCM program to continue indefinitely with the same level of intensity that it had during the primary intervention is neither practical for the person with T2D, nor economically sustainable for health systems. A recent systematic review of the cost-effectiveness of diabetes management interventions recommended by the American Diabetes Association and earlier reports have found DCM interventions to be cost-effective.[8–10] The 2020 review found a median of US$11,339 per quality-adjusted life year saved.[8] Nonetheless, long-term implementation of DCM represents a significant financial burden at a challenging time for sponsoring health systems relative to staffing resources and finances. It would be preferable to have a pared down, less intensive form of DCM post-completion of the intensive primary DCM intervention to serve as a scalable approach to sustaining glycemic gains which result from an intensive DCM program.

We have previously reported the results of a 3-month DCM program called Diabetes Boot Camp (DBC) developed to improve outcomes among diverse adults with T2DM with A1C >9% at entry.[6] The DBC intervention is initiated via a one-click electronic medical record (EMR) referral by the primary care provider (PCP), facilitated by remote blood glucose (BG) monitoring and weekly telehealth visits, initially with a CDCES and subsequently by a nurse practitioner (NP), for the provision of DSMES and T2D medications management. Improvement in pre/post-A1C (11.2%–8.1% in DBC participants compared with 11.3%–9.9% in concurrent chart controls, p value <0.001 for change in A1C comparison) and reduced risk of all cause hospitalization were demonstrated.[6] Having noted that gains in A1C began to wane during the 3–6 months after completion of the program, we set forward to develop, implement and evaluate a scaled-down ongoing DCM strategy which might enable maintaining those gains. Ideally, such an intervention, which we designate as a 'sustaining strategy', would be less time and labor intensive for both the PWD and the provider team while allowing for maintenance of the improved A1C achieved with the initial DCM strategy. We propose this important concept of a 'sustaining strategy' as a relatively lighter touch, ongoing check-in process for PWD who have successfully attained an A1C goal which will enable them to sustain glycemic improvements over time. In this study, we evaluate the 18 month impact on A1C of a novel 'sustaining strategy' follow-up program called Boot Camp-Plus (BC-Plus) which was offered to completers of a primary 3-month DCM intervention (DBC) implemented among ambulatory adults with T2D receiving care in a US regional healthcare system.

## DESIGN

Nine-month real-world quality improvement project with concurrent control group used in retrospective program evaluation of glycemic outcomes.

## METHODS

The DBC intervention was reviewed by the MedStar Health Research Institute Institutional Review Board and determined to be quality improvement and not research. All data extraction for purposes of program evaluation of

the DBC and BC-Plus was approved under a Health Insurance Portability and Accountability Act (HIPAA) waiver and waiver of informed consent.

## Participants

The DBC and BC-Plus programs were conducted in the MedStar Health system, a 10-hospital regional distributed healthcare delivery system. The system serves a culturally and economically diverse population which spans urban, rural and suburban settings in the District of Columbia and Maryland. MedStar Medical Group has 46 primary care practice groups from which DBC participants were identified via the EMR or by the PCP and referred for participation in that program. The main eligibility criteria for the DBC were current A1C >9.0% and ongoing receipt of primary diabetes care in the health system. Insurance of any type was required for DBC and uninsured status was an exclusion criteria. On completion of DBC, participants with Medicare or health system insurance (either a Medicaid plan administered by the health system or a health system sponsored employee commercial insurance) were offered the opportunity to enroll in a follow-on sustaining strategy check-in program called BC-Plus for an additional 9 months. The insurance eligibility criteria for BC-Plus were in line with the health system's priorities and the sustaining strategy program was not offered to DBC completers who did not have the system-designated insurances. This latter group of completers was referred to their primary diabetes care provider for ongoing diabetes care and comprise a portion of the control group in the analyses for this report. DBC completers who were offered BC-Plus and declined to participate were also included in the control group.

## Technology

All participants had cellular-enabled BG meters (BioTel BGM, Concord, Massachusetts, USA) which auto-transmitted BG data to a provider dashboard in near real-time allowing for remote glucose monitoring and capture of high and low BG events via a remote monitoring center dashboard.

## Boot Camp-Plus Sustaining Strategy Intervention

The overarching objectives of the BC-Plus intervention were to maintain participant A1C at the health system mandated Healthcare Effectiveness Data and Information Set (HEDIS) A1C target of <8%,[11] BG in a target range of 80–200 mg/dL, and to have high (repeat BG >300 mg/dL) and low (any single BG <40 mg/dL or repeat BG <80 mg/dL) BG events (Hi/Lo) identified and addressed by the PWD and/or the BC-Plus team.

The sustaining strategy intervention was initiated as a 9-month add-on period following completion of the primary 3-month DBC intervention. Timelines are shown in figure 1. The sustaining strategy was structured sequentially at two levels over a total of 9 months. The first level lasted for 3 months and the second level for 6 months. The content of the check-in calls by level is shown in tables 1–3. The key difference between level 1 and level 2 monitoring was continuation of daily remote BG monitoring for extreme high and low BGs during level 1. This service was not offered at level 2.

### Boot Camp-Plus level 1 check-in

During the first 3 months, participants received monthly follow-up calls by a medical assistant (MA) and continued to be remotely monitored daily (Monday–Friday) for Hi/Lo BG by the remote monitoring center staff. Participants were instructed to call the monitoring center during business hours and their own provider outside business hours for concerns regarding BG readings. Specifically, they were instructed to reach out if they experienced: (1) two or more unexplained BG <80 mg/dL in a 24-hour day; (2) BG <80 mg/dL at the same time of day on 2 days in a row; or (3) any BG <40 mg/dL or >300 mg/dL; symptoms of low BG even if BG was not checked; and/or for any diabetes-related concerns.

**Boot Camp-Plus level 1 and level 2 monthly check-in call procedures** (table 2) were conducted by a trained MA. Once a month, the MA reviewed all BC-Plus participants' BG results on the dashboard and provided scripted responses (table 3) based on BG levels via telephone call. All encounters were documented in EMR templates developed by the multidisciplinary team (physicians, CDCES, NPs, MA).

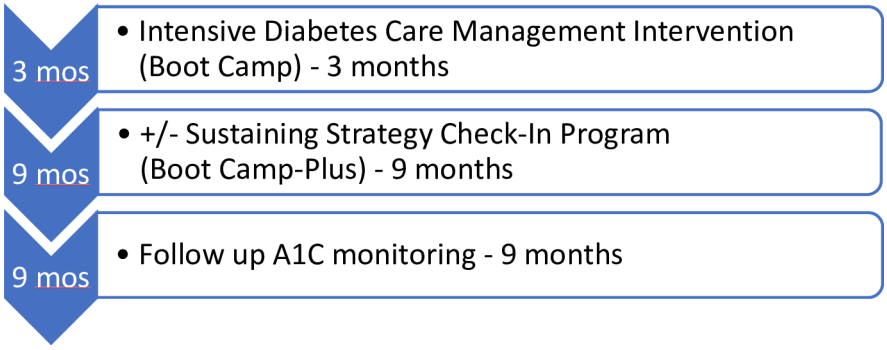


**Figure 1** Boot Camp-Plus activities timeline.

Table 1 Boot Camp-Plus intervention check-in activities by level

| BC-Plus | Level 1 | Level 2 |
|---|---|---|
| Follow-up months | Months 3–6 | Months 6–12 |
| Activities | Monthly MA call/ check-in | Monthly MA call/ check-in |
| | *Daily remote* glucose monitoring | *Daily self*-glucose monitoring<br>Monthly remote glucose monitoring |

BC-Plus, Boot Camp-Plus; MA, medical assistant.

The MA also inquired whether anything was needed to facilitate self-care and encouraged participants to continue making positive lifestyle choices, take their medications, and check BG levels. The MA ensured they had their next routine PCP follow-up visit scheduled within 3 months. If not, encouragement to schedule the visit was provided. Participants not checking BGs were asked if they needed supplies. If not, they were asked if they would be willing to check at least once or twice daily or as prescribed for the next month in order to receive feedback on their BG management. If they were out of meter supplies, the MA assisted with orders. Participants no longer using the BioTel meter were informed that remote monitoring would no longer be possible, and the PCP was notified that BC-Plus follow-up had ended. For participants 'above/below range' noted during regular BG surveillance or during check-in calls, the MA escalated the patient to the monitoring center NP via a flagged message in the EMR that included the most recent BG remote monitoring log or patient reported BG data. Escalation to the NP was also triggered in response to need for prescriptions, medication side effects and any additional instances where a higher level of care was felt needed by the MA.

### Boot Camp-Plus level 2 check-in

After the level 1 period had ended, daily remote glucose monitoring by the clinical team ended. During the level 2 period, participants received monthly follow-up calls with review of remote glucose data. They were asked to self-log any Hi/Low BG events and note the associated circumstances for discussion during monthly calls. The MA reviewed the BG dashboard prior to calling the participant and continued to provide the support outlined in tables 2 and 3. In addition, the MA documented any single BG <40 mg/dL, repeat BG <80 mg/dL and repeat BG >300 mg/dL. For individuals with two or more BG <80 mg/dL or BG >300 mg/dL, any BG <40 mg/dL, started on steroids, or exhibiting symptoms of illness, the MA escalated the process to the NP of record via a flagged message via the EMR alerting them to the BG excursions and any related information provided in response to the scripted questions. The NP would then check-in with the participant and provide interventions including T2D medication management, addressing intercurrent illness sick day rules, and further education as needed.

### BC-Plus additional activities

During the level 1 and 2 periods, additional support was provided by the MA. If A1C >9.0% was noted during regular chart reviews, escalation was provided to the remote monitoring center NPs. If no A1C had been obtained in the past 3 months, an EMR message was sent to the provider requesting an A1C check at the next visit. Prior to an upcoming scheduled visit with the provider, a copy of the most recent 2-week BG log was scanned into the EMR and a flag sent to the provider alerting them to review the data. Finally, the NPs were informed of any

Table 2 Monthly check-in procedures by blood glucose level

| Blood glucose status | Level 1<br>Remote monitoring criteria | Level 2<br>Patient report criteria | Procedures |
|---|---|---|---|
| In target range | Average BG <200 mg/dL<br>No BG <80 mg/dL<br>No BG >350 mg/dL | No repeat BG >300<br>No single BG <40 mg/dL<br>No repeat BG <80 mg/dL | ► MA reviews recent A1C and BG data<br>► MA provides positive reinforcement on continued BG checks and maintaining in range BG levels |
| Above target range (Hi) | A1C >9.0% or average monthly BG >200 mg/dL | Repeat BG >300 mg/dL | MA escalates to the monitoring center NPs via a flagged message in the EMR that includes the most recent BG log or reported data |
| Below target range (Lo) | BG <80 mg/dL | Any single BG <40 mg/dL or repeat BG <80 mg/dL | |
| Not checking | No BG data available | No BG data reported | MA inquires about perceived barriers to BG monitoring and assists with resolution if possible |

BG, blood glucose; EMR, electronic medical record; MA, medical assistant; NP, nurse practitioner.

Table 3 Level 2 monthly check-in scripted questions

| Blood glucose status | Scripted questions |
|---|---|
| Above target range (Hi) | ► What do you think happened on those days to make your sugars high?<br>► Did you take all the diabetes medications ordered by your doctor?<br>*If on mealtime insulin*:<br>Did you take your meal insulin?<br>Did you take your meal insulin right before you ate?<br>If not, did you take it at the end of the meal or after that?<br>Did you eat more than usual at that meal?<br>► Did you drink any sugary beverages (sweet tea, regular soda, juice)?<br>► Are you sick?<br>► Are you under a lot of stress?<br>► Have you been started on any medication that might make your sugars go up, For example, steroid injection in your joint, or solumedrol pack or cortisone or prednisone?<br>► Do you need refills for your diabetes medicines?<br>► Do you need insulin syringes or pen needles?<br>► Are you having any difficulty getting your DM medications? |
| Below target range (Lo) | ► What do you think happened to make your sugars low?<br>► Did you eat less than usual?<br>► (*If on meal time insulin*) did you eat when you took your meal time insulin?<br>► Were you more active than usual?<br>► Are you sick?<br>► Are you unable to eat?<br>► Do you have any difficulty with buying or getting food to eat? |
| Not checking | ► I see that you have not checked your blood sugar in the last 7 days, can you tell me why?<br>► Are you out of test strips?<br>► Are you using another BG meter now?<br>► Is your meter not working properly? |

BG, blood glucose.

hospital admissions or ER visits that were noted during the check-in calls.

### BC-Plus closeout activities

At the conclusion of the sustaining strategies period, participants were informed over the phone and by letter that the monthly check-ins would stop and were advised to continue regular follow-up with their PCP. The referring PCP received an EMR communication to that effect. The MA also verified that participants had their testing supplies, diabetes medications and a follow-up appointment with their PCP to ensure continuity of diabetes care and support.

### Post-BC-Plus A1C surveillance

A1C data were tracked for an additional 9 months following completion of the BC-Plus intervention period.

### Data management

A dedicated REDCap electronic data capture database[12] hosted by MedStar Health Research Institute was used by the program staff for tracking administrative tasks related to all participants in the DBC and BC-Plus programs.

### Statistical analyses

All consecutive participants completing the primary DBC care management program from March 2019 to July 2021 and their initial DBC visit date were abstracted from the REDCap database. This information was then used to extract demographic and follow-up outcomes data from the system Cerner EMR via query of the MedStar Analytics Platform (MAP)—the data warehouse underlying the EMR. BC-Plus participant status was assigned as indicated in the REDCap database. Control participants consisted of those who had declined to participate or were not offered the opportunity to participate due to non-Medicare/non-Health system insurance. The same query was used to extract outcomes data from the MAP regardless of control versus BC-Plus status.

All analyses were conducted using SAS V.9.4 (SAS Institute, Cary, North Carolina, USA). The independent variable was BC-Plus versus control status. The primary outcome variable was A1C at 3-month intervals starting from the DBC period (months 0–3) through the BC-Plus period (months 3 to 12) and out to 9 months after completion of BC-Plus (months 12 to 21). Descriptive analyses of demographic variables used frequency with percentage for categorical variables and mean with SD for continuous variables. A longitudinal linear mixed effects analysis[13] was used to estimate mean A1C trend over time in each group. The model used group-specific compound symmetry covariance to account for repeated A1C measures in the same participants over time and

Table 4 Cohort baseline demographics and insurance

| | BC-Plus (n=281) | Controls (n=557) | P value |
|---|---|---|---|
| Age, mean (SD) | 56.3 (11.7) | 55.7 (11.8) | 0.5 |
| Race/ethnicity (%) | | | 0.98 |
| Black (non-Hispanic) | 66.5 | 66.1 | |
| White (non-Hispanic) | 25.6 | 26.2 | |
| Hispanic | 1.4 | 1.8 | |
| Other | 5.0 | 5.0 | |
| % Female | 59.8 | 57.5 | 0.81 |
| % Insurance | | | 0.001 |
| Medicare | 38.4 | 26.7 | |
| Medicaid | 43.8 | 23.5 | |
| Private | 11.0 | 37.0 | |
| Other | 4.3 | 9.9 | |

generated p values for the difference in least squares means between groups at each follow-up time interval. All participants with at least one A1C after baseline were included in the analyses as this approach allowed for varying numbers and times of follow-up A1Cs. We assumed the A1C data were missing at random and the maximum likelihood estimation was used to handle missing data.

## RESULTS

Eight hundred and thirty-eight adults who were DBC completers were identified and eligible for this study. Among these, 281 met eligibility criteria and agreed to participate in the BC-Plus sustaining strategies program and 557 served as controls. The majority of participants were of African American race and female. There were no significant differences between BC-Plus participants and controls with regard to age, race/ethnicity, and gender. There was a higher proportion of patients with Medicare or Medicaid insurance among BC-Plus participants as shown in table 4. At month 0, the start of Diabetes Boot Camp, both groups were experiencing similarly elevated levels of A1C, p=0.09, and both groups achieved similar A1C improvement by month 3, the end of the intensive Diabetes Boot Camp care management intervention (p=0.07) (table 5).

### Longitudinal glycemic outcomes

Glycemic outcomes over time are shown in table 5 and figure 2. The total analysis period was 21 months. The mixed effects model found that participants in the BC-Plus group (n=281) experienced better glycemic control (A1C) compared with controls (n=557) throughout the BC-Plus 9-month check-in period, as well as for an additional 9 months beyond completion of BC-Plus, though by the end of the post-BC-Plus period, the p value is of borderline significance. The mean A1C stayed under 8.0% for the BC-Plus group through 6 months after completion of the BC-Plus sustaining strategy, after which, it rose to 8.18%.

Both groups experienced further reduction in A1C during the first 3-month period following BC completion with a nadir of 7.28% for BC-Plus participants and 7.65% for controls. After this initial period, the mean A1C for controls began to increase and reached over 8.0% by 6 months after completion of the intensive DBC intervention. The difference in mean A1C between BC-Plus and control participants was statistically significant during the entire sustaining strategies period.

## DISCUSSION

The findings of this study are consistent with a positive impact of a novel sustaining strategy check-in program delivered as follow-up to an intensive DCM program on longitudinal glycemic control. The lighter touch

Table 5 Long-term A1C improvement sustainability outcomes: mean A1C and differences by mixed effects analysis (adjusted for insurance status)

| | BC-Plus (%) | Controls (%) | Difference | P value* |
|---|---|---|---|---|
| 0 month (Baseline Boot Camp visit) | 11.0±0.10 | 11.22±0.08 | 0.24 | 0.09 |
| 3 months (end of Bootcamp/Start of BC-Plus) | 7.81±0.13 | 8.13±0.10 | 0.33 | 0.07 |
| 6 months | 7.28±0.13 | 7.65±0.09 | 0.37 | 0.04 |
| 9 months | 7.52±0.14 | 8.23±0.11 | 0.71 | 0.002 |
| 12 months (end of sustaining strategy) | 7.78±0.14 | 8.36±0.11 | 0.58 | 0.007 |
| 15 months | 7.72±0.15 | 8.63±0.11 | 0.91 | 0.0005 |
| 18 months | 7.78±0.14 | 8.50±0.11 | 0.68 | 0.004 |
| 21 months | 8.18±0.16 | 8.61±0.12 | 0.43 | 0.054 |

*Comparison of the difference of mean A1C between groups at each follow-up time.

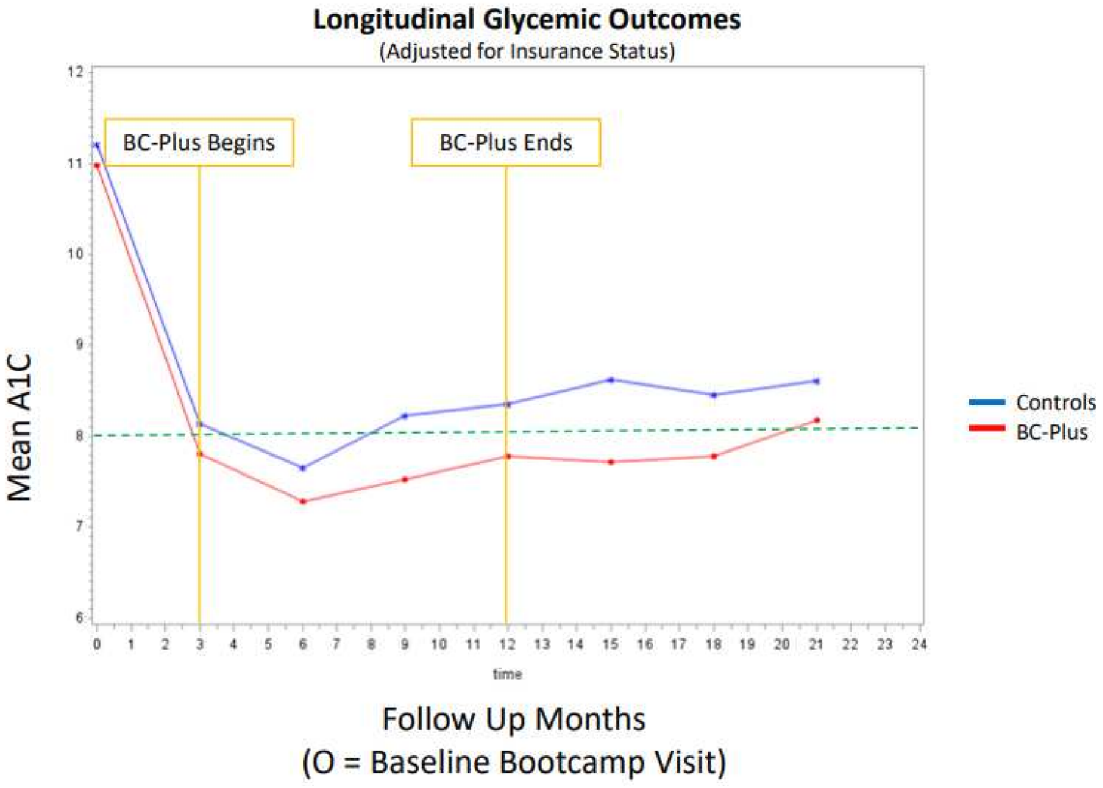


**Figure 2** Long-term post-intensive diabetes care management intervention A1C outcomes: Boot Camp-Plus (BC-Plus) sustaining strategy versus controls by mixed effects analysis (adjusted for insurance status).

sustaining strategy, BC-Plus, which offered once monthly follow-up check in visits by phone and 3 months of active daily remote BG monitoring, enabled participants to maintain an A1C <8.0% out to month 18 of follow-up, 15 months after the completion of a 3-month high-intensity DCM intervention. This enabled maintaining reasonable glycemic targets per current American Diabetes Association Standards of Medical Care for Type 2 Diabetes[14] for the intervention cohort given that the mean age was 56 years and that it meets the health system-targeted HEDIS metric of <8% for adults with T2DM. Without the sustaining strategy and despite a greater proportion having private insurance in the control group, A1C rose from its nadir of 7.65% at month 6 to over 8% by month 9—just 6 months after completing the intensive intervention. This evidence supports the need for a sustaining strategy to be implemented following completion of an intensive type 2 DCM program to maintain improvements in A1C obtained as a result of that program. The data presented suggest that a sustaining strategy needs to be reinitiated by 6 months following completion of the monthly check-in strategy, and/or that a system for an ongoing perhaps even lighter touch check-in strategy and/or tracking A1C following program completion to identify persons whose A1C is beginning to rise, will be required to maintain gains in glycemic outcomes over time.

It is also of interest to note several other points regarding A1C in the study. That A1C levels continued to fall and reached their nadir for both the intervention and control groups at 3 months following completion of the intensive diabetes care management intervention is not surprising. The mean entry level A1Cs were just over 11% so the full impact of the intensive DCM intervention may not be captured in this metric in 3 months. It also demonstrates that the T2D self-care management education and medications management had an enduring effect to 3 months beyond completion of the intensive intervention for both groups regardless of whether participants received the follow-up intervention. It is also important to note that by 9 months after completion of the lighter touch sustaining strategy A1C did rise to over 8.0%. This observation argues for the need for an ongoing long-term support strategy in diabetes care management programs. Finally, in both the sustaining strategy check-in and control groups, A1C for the entire study period remained well below the markedly high levels found at entry to the intensive program, providing evidence of the concept of durability of intensive DCM interventions incorporating DSMES, MNT and medication management services.

In designing the BC-Plus intervention, we felt that any positive effect on glycemic outcome would be mediated in part via intensified medication management and associated PCP visits as evident in the level 1/level 2 check in call procedures including prompts for escalation to NP for medication management and PCP visits when appropriate. In support of these factors as part of the

mechanism for the positive impact of BC-Plus on glycemic control, we found that during post-BC follow-up (months 3 to 21) there were more PCP visits in the BC-Plus arm compared with controls (mean PCP visits of 4.2 vs 3.4).

We have characterized the positive intermediate-term glycemic control impact of BC-Plus, a novel example of a lighter touch monthly check-in sustaining strategy delivered remotely for 9 months to adults with T2DM following completion of a high-intensity DCM intervention. It is possible that similar deintensified support strategies would be effective in enabling maintenance of glycemic improvements seen with other high intensity DCM interventions in a cost-effective and thereby scalable fashion. The data also demonstrate a longer term durability of A1C improvement among all participants who completed a previously reported 3-month intensive diabetes care management program (DBC). The ability to maintain A1C below 8% waned 6–9 months following completion of the sustaining strategy check-in intervention, suggesting a need for some form of ongoing surveillance and/or intervention. Further studies will be needed to explore the design, implementation methodology and health economics of T2D care management sustaining strategies.

## LIMITATIONS

The BC-Plus intervention was designed and implemented as a quality improvement response to the observation of the waning benefit of A1C improvement in participants completing an intensive DBC. Hence, the assessment of the long-term impact on glycemic control of BC-Plus presented here is necessarily observational rather than randomized in design. This raises the possibility of unmeasured confounding as mediating our results rather than BC-Plus itself. However, both BC-Plus and control participants in this study had successfully completed an intensive initial DCM intervention and attained marked comparable A1C improvement arguing against confounding as the sole explanation of our findings. By design, the payer mix between BC-Plus participants and controls in the sustaining strategies period was not equivalent as the BC-Plus program was only offered to DBC completers who had Medicare and/or health system insurance. Hence, the BC-Plus group had a significantly higher proportion of Medicare and Medicaid insured participants. However, in both unadjusted and insurance status adjusted analyses, the BC-Plus participants had greater sustainability of A1C gains with stable glycemic outcomes regardless of adjustment for insurance status. This suggests that insurance status imbalance present in our cohort was not acting as a confounder.

Although mixed effects modeling has advantages for longitudinal outcomes with repeated measures and missing data,[13] whether the data is missing at random (MAR) or not is a limitation as the model assumes missing data is MAR. In our study, we had missing A1C data which did increase over time (10% at month 6; 37% by month 18) and more so in the control arm after month 9 of follow-up. Whether this data is MAR is unclear but it is plausible to assume that participants missing A1C checks are likely to have higher A1C than those not missing A1C checks. If this is the case, then the differential in missing A1C in longer term follow-up may bias the findings against a positive impact (or decrease the positive impact) on A1C of BC-Plus in the longer term follow-up timeframes examined in this report. Our finding of long-term positive impact of BC-Plus despite the limitation of missing A1C data argues for the robustness of positive impact of BC-Plus on glycemic control.

## CONCLUSIONS

Among completers of an intensive 3-month DCM intervention, participants in a low intensity 9-month check in sustaining strategy experienced significantly greater ability to maintain A1C under 8.0% (the HEDIS threshold for diabetes control), when compared with controls. In participants, this benefit was sustained until fully 18 months after completion of the intensive DCM intervention. In contrast, mean A1C in controls rose above 8.0% at only 6 months after completion of the intensive DCM intervention.

**Contributors** MM, CMN, and ARM are responsible for the conception, design and conduct of all aspects of the study. ARM acquired, had full access to and analyzed and interpreted the data. ARM, MM and CMN drafted the manuscript. ARM, MM, CMN and SA participated in critical revision of the manuscript for important intellectual content. ARM had primary responsibility for manuscript preparation; final responsibility for the decision to submit for publication; and is the author responsible for the overall content as guarantor.

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