FEATURE ARTICLE

Impact of Participation in a Virtual Diabetes Clinic on Diabetes-Related Distress in Individuals With Type 2 Diabetes

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The Onduo Virtual Diabetes Clinic is a telehealth program for people with type 2 diabetes that combines mobile app technology, remote personalized lifestyle coaching, connected blood glucose meters, real-time continuous glucose monitoring (rtCGM) devices, and clinical support from board-certified endocrinologists. This analysis evaluated change in diabetes distress among 228 program participants who reported moderate distress (score 2.0–2.9) or high distress (score $\geq$3.0) on the 17-item Diabetes Distress Scale (DDS17) at enrollment. Participants reported significant reductions in overall distress from 3.0 $\pm$ 0.8 at baseline to 2.5 $\pm$ 0.9 (P <0.001) at an average of 6 months of follow-up. Significant reductions in all DDS17 subscale scores were observed; most notable were reductions in the regimen-related and emotional distress subscales (−0.9 and −0.4, respectively; both P <0.001). Significantly greater reductions in overall distress (P = 0.012) and regimen-related distress (P <0.001) were reported by participants who were prescribed and used intermittent rtCGM (n = 77) versus nonusers (n = 151). Although the generalizability of these findings may be limited by the study's small sample size and potential for self-selection bias, these results do suggest that telemedicine programs such as the Onduo VDC could be a valuable tool for addressing the problem of diabetes-related distress.

Patient self-management is foundational to the effective treatment of diabetes. However, individuals with diabetes often feel overwhelmed by the numerous and often complex tasks required for daily self-care regimens (1). This results in frustration, fear, anger, and helplessness, often leading to impaired self-management (1). This wearying sense of burden is referred to as diabetes-related distress, a constellation of significant negative emotional reactions that many people have in response to their diagnosis, threat of complications, rigorous self-management demands, and/or lack of social support (1–5).

Diabetes-related distress affects a significant proportion of adults with type 2 diabetes (6,7). It is associated with suboptimal glycemic control (6,8–11) and a higher prevalence of complications (11,12). One recent study reported a significant positive association between elevated diabetes-related distress levels and all-cause mortality in men with diabetes (12). Importantly, investigators have observed a strong association between individuals with diabetes-related distress and diminished adherence to prescribed self-management regimens (6,8,9,13). In turn, reductions in diabetes-related distress over time have been linked to improved self-management and glycemic control (14).

Emerging evidence suggests that use of telemedicine technologies that support people in their daily self-management may improve clinical outcomes and reduce the burden of diabetes. A recent meta-analysis of 42 randomized controlled trials reported that interventions with telemedicine technologies are more effective, particularly in older individuals, than usual care in managing diabetes, especially in type 2 diabetes (15). As reported by Mora et al. (16), use of a connected blood glucose meter that automatically transfers data to clinicians for review and timely follow-up resulted in significant reductions in

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both A1C and diabetes-related distress in adults with insulin-treated type 2 diabetes. Similar improvements in diabetes-related distress and other psychosocial measures have been reported in earlier telemedicine studies (17,18).

The Onduo Virtual Diabetes Clinic (VDC) is a telehealth program for people with type 2 diabetes designed to support diabetes management in the primary care setting between office visits. The program combines mobile app technology, remote personalized lifestyle coaching from certified diabetes educators and health coaches, and connected tools and medical devices, including blood glucose meters and real-time continuous glucose monitoring (rtCGM) devices. Key differentiating features of the VDC care model are the availability of live video consultations with board-certified endocrinologists for medication management and the ability to remotely prescribe and ship rtCGM devices. The VDC care model includes evidence-based clinical escalation protocols, which allow participants to transition between levels of health coaching, specialist education, and telemedicine consultation dynamically based on their risk profiles and needs. Use of rtCGM technology, which is emerging as a standard of care for diabetes management, is unique to the VDC program. The current analysis examines the impact of participation in the VDC on diabetes-related distress.

Research Design and Methods

VDC Program

The VDC telehealth technology and care model have been previously described in detail (19). Briefly, the VDC is available to adults with type 2 diabetes who are members of payor and employer health plans that sponsor the program throughout the United States. Those who elect to enroll then download the VDC app to their smartphone, provide demographic and clinical information, complete baseline surveys, and are mailed a self-management kit that includes a cellular-connected glucose meter (Telcare, Malvern, PA), test strips, and a home A1C testing kit (DTI Laboratories, Inc., Thomasville, GA). Participants interact with their care team primarily through the VDC app, with occasional phone calls, and by video consultations with endocrinologists, as clinically appropriate. The VDC app tracks data relevant to participants' diabetes care, including glucose readings, medication, and physical activity and meal data. High-risk individuals are prescribed rtCGM (Dexcom G5/G6, Dexcom, San Diego, CA) for intermittent use over several months.

Study Design and Participants

This retrospective, exploratory analysis evaluated change in diabetes-related distress associated with participation in the Onduo VDC program among participants who enrolled from August 2018 through April 2019 and completed follow-up survey responses from April through August 2019. Participants were included in the analysis if they completed the DDS17 during the enrollment process (baseline), reported moderate or greater distress upon enrollment, and then subsequently completed a second DDS17 survey at follow-up (after ≥3 months of program participation). Both baseline and follow-up questionnaires were sent electronically via the VDC app. Completion of the DDS17 was optional and not required for program participation; therefore, only the subset of program participants who completed both the baseline and follow-up questionnaires were included in these analyses.

Of note, a significant proportion of the participants were prescribed rtCGM for intermittent use. These participants typically were in suboptimal glycemic control (A1C ≥8.0%) and/or were at risk for hypoglycemia (i.e., used insulin or a sulfonylurea) and/or had repeated hypoglycemia or hyperglycemic episodes as identified by the connected glucose meter. This analysis was approved by the Western Institutional Review Board for waiver of consent.

Outcomes

The DDS17 assesses patient-perceived difficulties and concerns related to diabetes experienced during the past month (8). Responses are graded on a Likert scale (from 1 = not a problem to 6 = very serious problem). The completed questionnaire yields a composite distress score and four subscale scores highlighting key areas of concern: regimen-related distress (e.g., "feeling that I am often failing with my diabetes routine"), emotional burden (e.g., "feeling that I will end up with serious long-term complications, no matter what I do"), interpersonal distress (e.g., "feeling that friends or family don't appreciate how difficult living with diabetes can be"), and physician-related distress (e.g., "feeling that my doctor doesn't take my concerns seriously enough"). A composite mean score of <2.0 indicates little or no distress, a mean score from 2.0 to 2.9 indicates moderate distress, and a mean score ≥3.0 indicates high diabetes-related distress.

Statistical Analysis

Characteristics of survey respondents and participants who did not complete the follow-up survey were summarized and compared. All subsequent analysis was performed for the survey respondents. Two-tailed t tests were used to examine change in DDS17 composite score (overall) and subscale scores over the follow-up period. A multivariate linear regression model was applied to examine the potential influence of key baseline factors on DDS17 score at follow-up, after controlling for baseline DDS17 score. The model included all survey respondents and examined baseline factors of age, BMI, sex, geographic location, insulin use, and rtCGM use. Two-sample t tests investigated whether DDS17 change was significantly different between participants with moderate versus severe distress at baseline and between rtCGM users versus nonusers of rtCGM. All statistical analyses were performed using Python, v. 2.7.16, statistical software (Python Software Foundation, Wilmington, DE). Statistical significance was defined as P <0.05 for all comparisons.

Results

Of the 735 participants who had an initial DDS17 score ≥2.0, indicating at least moderate distress, 228 participants completed the follow-up survey. Mean follow-up was 179.4 ± 74.0 days. Demographic and clinical characteristics of the survey completers and noncompleters are presented in Table 1. Respondents were predominantly female (73.2%), mean baseline BMI was 36.8 kg/m^2, and mean A1C was 8.3%. At enrollment, 39.5% of participants were using insulin. More than one-third of participants were provided with an rtCGM device for intermittent use. Participants who completed the follow-up survey were significantly more likely to make use of the connected blood glucose meter than those who did not complete the follow-up survey. Completers were also significantly more likely than noncompleters to be prescribed rtCGM. Of note, baseline characteristics were generally similar for users and nonusers of rtCGM.

Changes in Diabetes-Related Distress

There was a significant reduction in overall DDS17 score over the observation period, from 3.0 ± 0.8 at baseline to 2.5 ± 0.9 (P <0.001) at follow-up (Figure 1). Significant reductions in all four subscales were also observed, with the most notable reductions in regimen-related and emotional distress. When stratified by moderate (n = 137) or severe (n = 91) distress at baseline, reductions in overall distress were reported by both groups (−0.1 ± 0.7 [P = 0.021] and −1.0 ± 0.9 [P <0.001], respectively).

rtCGM Use

Diabetes-related distress improved significantly in both users and nonusers of rtCGM, but subgroup analyses pointed to a significantly larger decrease in overall DDS17 scores and regimen-related distress among rtCGM users compared with nonusers (Table 2). Of note, overall DDS17 scores were similar for users and nonusers of rtCGM at baseline (3.1 ± 0.8 and 2.9 ± 0.8, respectively). However, both regimen-related and emotional burden at baseline were significantly higher in the rtCGM use group compared with the nonuser group (4.0 ± 1.0 vs. 3.7 ± 1.0

TABLE 1 Participant Characteristics

	Survey Completers* (n = 228)	Survey Noncompleters (n = 448)	P
Age, years	51.8 ± 9.5	50.3 ± 10.0	0.060
Female, n (%)	167 (73.2)	291 (65.0)	0.029
BMI, kg/m^2	36.8 ± 8.6[a]	36.5 ± 9.0[d]	0.705
Baseline A1C, %	8.3 ± 1.9[b]	8.4 ± 2.1[e]	0.517
Baseline DDS17 overall score	3.0 ± 0.8	2.9 ± 0.8	0.226
Medication use, n (%)			
Sulfonylurea	57 (25.0)	101 (22.5)	0.476
Insulin	90 (39.5)	159 (35.5)	0.310
Connected blood glucose meter use, n (%)	216 (94.7)	255 (57.0)	<0.001
rtCGM use, n (%)	77 (33.8)	35 (7.9)	<0.001
Geography, n (%)			0.410
Urban	170 (75.9)[c]	333 (78.7)[f]	
Rural	54 (24.1)[c]	90 (21.3)[f]	

Data are mean ± SD unless otherwise indicated. *n = 59 participants did not fully complete the follow-up survey and were excluded from the analysis. [a]n = 223. [b]n = 132. [c]n = 224. [d]n = 426. [e]n = 150. [f]n = 423.

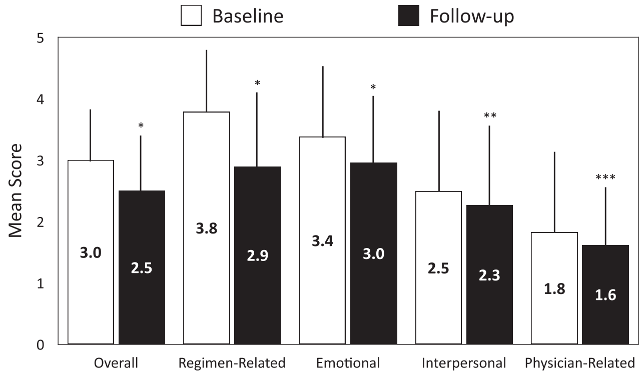

FIGURE 1 Changes in DDS17 overall score from baseline to follow-up (n = 228). *P <0.001. **P = 0.002. ***P = 0.006.

[P = 0.044] and 3.6 ± 1.0 vs. 3.3 ± 1.1 [P = 0.046], respectively).

In a regression analysis of all survey respondents (n = 228), older age (β = −0.014 per year, P = 0.013) and rtCGM use (β = −0.217, P = 0.048) were significantly associated with lower overall DDS17 scores at follow-up, after controlling for baseline DDS17 score (β = 0.459, P <0.001) (Table 3).

Discussion

These early findings suggest that participants in the Onduo VDC who reported clinically relevant levels of diabetes-related distress on enrollment experienced a significant reduction in diabetes-related distress over 6 months of participation, notably in regimen-related and emotional distress. Significant improvement was observed in the subset of participants with only moderately elevated distress at baseline, as well as in those with more severe distress. However, it would appear that the reductions in distress were only clinically meaningful in the latter group, which suggests that the VDC is particularly useful in more severely distressed individuals. We suspect that the ongoing individualized lifestyle and clinical support provided by the VDC care team may be key contributors to these reported benefits. Of note, we found that improvement in overall distress was independently associated with rtCGM use and older age.

TABLE 2 Change in DDS17 Scores: rtCGM Use Versus No rtCGM Use

	Nonusers of rtCGM (n = 151)	Users of rtCGM (n = 77)	P
Overall	−0.4 ± 0.9	−0.7 ± 0.8	0.012
Regimen-related	−0.7 ± 1.3	−1.3 ± 1.2	<0.001
Emotional burden	−0.3 ± 1.2	−0.6 ± 1.1	0.06
Interpersonal concerns	−0.2 ± 1.1	−0.4 ± 1.2	0.13
Physician-related	−0.2 ± 1.0	−0.2 ± 1.2	0.73

TABLE 3 Multivariate Linear Regression Model of the Impact of Baseline Characteristics on Final DDS17 Score

	Final Multivariable Model (n = 228)		
	β	SE	P
DDS17 score	0.459	0.07	<0.001
Age	−0.014	0.01	0.013
rtCGM use	−0.217	0.11	0.048
Results When Each Term Is Added Individually to the Final Multivariable Model			
Insulin use	0.179	0.11	0.098
BMI	−0.009	0.01	0.140
Female sex	0.143	0.12	0.224
Geographic location	0.097	0.12	0.425

The intermittent use of rtCGM prescribed by VDC endocrinologists is an important differentiating feature of the Onduo program compared with other telehealth programs (20). The recent DIAMOND (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) trial reported significant improvement in A1C in insulin-requiring adults with type 2 diabetes using rtCGM compared with usual care over 24 weeks (21,22). However, diabetes-related distress in the DIAMOND trial did not improve in rtCGM users compared with the control group who did not use rtCGM. This finding stands in contrast to the current study, in which participants who used intermittent rtCGM reported a nearly twofold greater improvement in diabetes-related distress compared with nonusers of rtCGM.

Three factors may be at play here. First, participants in the DIAMOND trial wore a rtCGM device continuously for the 6-month intervention but received only limited guidance about how to interpret and make good use of the resulting data. Quite differently, rtCGM in the VDC program was only used intermittently, but personalized feedback and problem-solving were provided in response to observed glucose patterns. This difference highlights the potential importance of individualized coaching and clinical support in conjunction with rtCGM use as a key contributor to reductions in distress. Second, DIAMOND trial participants represented a much less distressed population (mean DDS17 score = 1.9) than participants in the current study, who were selected because of their elevated scores (mean DDS17 score = 3.0). Because of floor effects, it may only be reasonable to expect a diabetes-related distress benefit after an intervention when there is sufficient room for improvement, as has been previously observed (23). Finally, unlike in the DIAMOND trial, rtCGM use versus nonuse in the current study was not the result of random assignment and therefore was subject to self-selection bias. Only higher-risk participants were prescribed rtCGM, and this finding is reflected in the observed differences at baseline between rtCGM users and non-users in the two crucial DDS17 subscales (emotional burden and regimen-related distress).

The findings of this analysis may also have positive implications beyond distress reduction. As reported by Hessler et al. (14), reductions in regimen-related distress have been associated with improvements in both self-management and A1C over 12 months. Although glycemic outcomes were not evaluated in this cohort, a recent study of 740 VDC participants, stratified by baseline A1C levels of >9.0, 8.0 to 9.0, and 7.0 to <8.0%, reported that A1C decreased significantly by 2.3 ± 1.9, 0.7 ± 1.0, and 0.2 ± 0.8%, respectively (all P <0.001) (19). Although additional study is needed, these results suggest a potential association between participation in the VDC and improvement in clinical and self-reported outcomes for people with type 2 diabetes.

We recognize that there are significant methodological limitations to this exploratory analysis, and we therefore recommend caution when interpreting these findings. Most importantly, without a control arm to the study, we cannot be certain that the observed drop in diabetes-related distress was the result of the intervention itself rather than a regression to the mean, especially given that all participants had elevated levels of distress at baseline. It is noteworthy, however, that chronic diabetes-related distress has been found to be relatively stable over time when no intervention occurs (24). An additional concern is the limited number of respondents (31%) who completed the follow-up DDS17. This may point to a possible self-selection bias because participants who experienced reductions in distress may have been more likely to complete the follow-up questionnaire. Also, the significantly lower use of the connected blood glucose meter and rtCGM in the noncompleter group point to lower program engagement. Despite these limitations, the study results suggest that participation in the VDC program may indeed contribute to significant reductions in clinically relevant distress and that further study is warranted.

Primary care physicians see approximately 90% of all adults with type 2 diabetes (25,26), and they will be increasingly challenged to provide effective chronic care to this population within the constraints of our current acute care model of health care delivery. Moreover, tightening metrics for quality of care and physician performance will negatively affect physicians who are unable to meet these new standards. Thus, developing tools and strategies to identify and alleviate diabetes-related distress, a known psychological obstacle to effective self-management behaviors and subsequent achievement of desired glycemic control (27,28), will be of great value in addressing both the medical and psychological needs of the growing diabetes population.

The results of this study suggest that telemedicine programs such as the Onduo VDC, by supporting individuals with diabetes and their clinicians in their diabetes management efforts, could be a potentially valuable tool for addressing the problem of diabetes-related distress.

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DUALITY OF INTEREST

W.H.P. has served as a consultant for Abbott, AstraZeneca, Dexcom, Insulet, Intarcia, LifeScan, Lilly, Novo Nordisk, Onduo LLC, Roche, and Sanofi. J.E.L., N.A.B., and R.F.D. are employees of Onduo LLC, a joint venture of Verily Life Sciences and Sanofi. C.G.P. has received consulting fees from Abbott Diabetes Care, Dexcom, Diasome Pharmaceuticals, CeQur, LifeScan, Onduo LLC, and Roche Diabetes Care. C.M.K., D.P.M., and H.Z. are employees of Verily Life Sciences.

AUTHOR CONTRIBUTIONS

W.H.P., J.E.L., and C.G.P. wrote the initial draft of the manuscript. C.M.K., N.A.B., D.P.M., H.Z., and R.F.D. analyzed the data. All authors contributed to the study design and analytic plan, reviewed and edited the manuscript, and approved the manuscript for submission. R.F.D. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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