Published in final edited form as:

Diabetes Educ. 2020 June ; 46(3): 289–296. doi:10.1177/0145721720913276.

Does diabetes distress influence clinical response to an mHealth diabetes self-management education and support intervention?

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Abstract

Purpose: The purpose of this study was to examine whether baseline levels of DD impacted clinical benefit from a mobile health diabetes self-management education and support (DSME/S) intervention ("Dulce Digital").

Methods: This secondary analysis included the full sample of N = 126 Hispanic adults (M age = 48.43 years, SD = 9.80) with type 2 diabetes and glycosylated hemoglobin A1C > 7.5% enrolled from a Federally Qualified Health Center in a randomized, non-blinded clinical trial that compared Dulce Digital to usual care. Dulce Digital participants received educational/motivational, medication reminders, and blood glucose monitoring prompt text messages over six months.

Results: Baseline levels of DD prospectively moderated the effect of Dulce Digital (versus usual care) on glycemic control over six months, such that Dulce Digital participants with higher DD experienced relatively greater benefit from the intervention. The effect of the intervention on A1C change was 178% larger among individuals experiencing moderate/high versus no/low DD.

Conclusions: Although research has found DD to be associated with poorer self-management and clinical outcomes, individuals already distressed about their diabetes may benefit from a lower-burden mHealth DSME/S approach.

Trial Registration: ClinicalTrials.gov Identifier: NCT01749176

Diabetes is a chronic metabolic condition that affects 30.3 million people in the U.S., and type 2 diabetes (T2DM) constitutes the vast majority (90–95%) of these cases.[1] The International Diabetes Federation projects an approximate 50% increase in diabetes rates by the year 2045.[2] While the alarming increases in prevalence have been observed globally, the U.S. has one of the highest diabetes prevalence rates among developed nations for individuals 20–79 years of age.[2] Within the U.S., significant disparities in the prevalence of diabetes have been observed in socioeconomically disadvantaged, racial/ethnic minority

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The authors do not have any conflicts of interest to declare.

populations. Further, Hispanics/Latinos (hereafter “Hispanics”) have a higher risk of developing diabetes,[1] and also exhibit poorer diabetes control[3] and outcomes[4] compared to non-Hispanic whites.

Emotional distress, including depression and disease-specific distress, have been shown to contribute to poorer outcomes in T2DM.[5,6] Diabetes distress (DD) is defined as the negative emotional burden individuals with diabetes experience due to living with, and managing, a demanding, chronic condition. A 2017 systematic review and meta-analysis of 55 studies (N = 36,998) demonstrated an overall DD prevalence of 36% among individuals with T2DM.[7] Although DD and depression are correlated, studies have identified important distinctions between the two conditions. In addition to being more common,[8] DD also appears to have stronger and more consistent associations with poorer diabetes self-care and suboptimal glycemic control than does depression.[9,10]

Due to the widespread prevalence of DD and its demonstrated impact on behavioral and clinical diabetes outcomes, the American Diabetes Association (ADA) has recommended that care teams routinely monitor DD using validated measures.[11] Per ADA guidelines, patients exhibiting DD should be referred to diabetes self-management education and support (DSME/S) to “address areas of diabetes self-care that are most relevant to the patient and have the most impact on diabetes outcomes” (p. 2132[11]). While DSME/S has been established as a critical component of effective diabetes care, utilization is low (<5% of individuals with diagnosed diabetes),[10] and many at-risk individuals are unable to access face-to-face DSME/S services due to practical (e.g., work, transportation, caregiving) and healthcare access barriers.[12–15] Given the widespread and increasing use of mobile phones in the US,[16] mobile health [mHealth; e.g., telehealth, short messaging services (SMS), mobile applications] has the potential to circumvent many practical barriers to in-person DSME/S and extend the reach of this resource. A recent synthesis of systematic reviews found that mHealth DSME/S interventions significantly improved glycosylated hemoglobin A1C,[17] and preliminary research has reported the same finding in underserved, minority populations, including Hispanics.[18–20]

While evidence supporting the clinical effectiveness of DSME/S interventions is evident, less is known about if and/or how DD influences the degree to which patients benefit from DSME/S. Some preliminary qualitative research suggested that (mHealth) DSME/S increased patient awareness of their condition, thereby intensifying feelings of distress and potentially leading individuals to react negatively to an intervention.[21] Given that DSME/S has been recommended as the first line approach for individuals with DD, further research is warranted and could hold important implications for practice. For instance, findings could suggest a need to tailor DSME/S to DD level, or perhaps shed light on which “types” of DSME/S work best for various emotional distress profiles. The current study aims to address this gap in the literature by investigating how baseline levels of DD impact clinical responsiveness to a mHealth DSME/S intervention (“Dulce Digital”) in Hispanic adults with T2DM.

Dulce Digital is a culturally-tailored DSME/S intervention delivered via SMS that was found to be effective in improving glycemic control over six months compared with usual

care (A1C Δ = −1.0% vs. 0.2%, $p = .03$) in underserved Hispanic individuals with poorly controlled T2DM.[18] The present study is a secondary analysis using data from the original randomized controlled trial to examine whether baseline levels of DD prospectively moderated the effect of the Dulce Digital DSME/S intervention on glycemic control (i.e., interaction effect). Given research suggesting that higher DD relates to worse diabetes outcomes overall,[9] we hypothesized that individuals reporting relatively higher levels of DD at baseline would exhibit significantly smaller clinical benefit (i.e., less A1C improvement) of Dulce Digital (versus usual care) than those reporting lower levels of distress.

Method

Data were collected as part of a larger, randomized, non-blinded clinical trial (hereafter, "parent study") that compared Dulce Digital versus usual care. A brief overview of the parent study methods is provided below. Additional information, including the CONSORT diagram, and detailed information on study procedures, clinical effectiveness, and participant-reported satisfaction with the *Dulce Digital* intervention are included in the primary outcomes paper.[18] The present analysis is distinct given that DD was not examined (as a moderator or an outcome) in the primary outcomes paper.[18]

Participants

A total of N=126 Hispanic adults (18–75 years of age) with T2DM and poor glycemic control (A1C > 7.5%) were recruited for the Dulce Digital trial from clinic sites within Neighborhood Healthcare, a network of federally-qualified health centers (FQHCs) in Southern California that serves a predominantly low socioeconomic status, ethnic/racial minority (majority Hispanic) patient population. Individuals with plans to move outside the region, or a severe physical or mental condition that would interfere with consent or intervention participation, were excluded.

Procedure

Potential participants were identified through a variety of methods, including provider referrals, electronic medical records review, and outreach flyers. Interested individuals were screened by phone by a bilingual, bicultural research assistant, and if eligible and interested, were scheduled for a baseline visit. At the initial visit, individuals received a detailed explanation of the Dulce Digital study requirements, and once all questions were answered, provided written informed consent. All procedures were approved by the Scripps Health Institutional Review Board.

Following the consenting process, a baseline assessment was conducted, which included blood draw with assay of A1C and a self-report survey with measures of sociodemographic factors and DD. All participants then viewed a 15-minute diabetes educational video, and received a blood glucose meter (OneTouch Verio® Meter, LifeScan Inc., Milpitas, CA) and testing strips prior to randomization to Dulce Digital or usual care. Participants in the Dulce Digital group received three variations of text messages—motivational, educational, and/or call-to-action (i.e., prompts to take medication and check blood glucose) —over a six-month period. The frequency of text messages was two-to-three per day, with tapering over the

course of the intervention. Blood glucose monitoring prompts encouraged participants to text message back their next observed value; out-of-range values prompted a bilingual study coordinator to call the participant and assess possible reasons for hyper/hypoglycemia, encouraging as-needed follow up with a medical provider. Usual care services available to all patients included visits with a primary care physician, certified diabetes educator and group DSME/S; however, utilization of the services was dependent on physician and patient initiative. Clinical and DD assessments were repeated at three and six months following the baseline.

Measures

Diabetes Distress.—DD was measured using the 17-item Diabetes Distress Scale (DDS[22]) in each participant's preferred language, English or Spanish. Respondents self-reported the extent to which they had experienced distress across four domains (i.e., emotional burden [five items], physician-related distress [four items], regimen distress [five items], and diabetes-related interpersonal distress [three items]) over the last month using a six-point likert scale (1, "not a problem" to 6, "a very serious problem"). Responses to all 17 items were averaged to create a total DDS score for each participant, with higher scores indicating greater levels of distress. The DDS has been translated to Spanish[23] and has been shown to have good psychometric properties and to relate to self-care behaviors and glycemic control in prior research.[24] In this sample, both the Spanish ($\alpha = 0.94$) and English ($\alpha = 0.96$) forms of the DDS demonstrated high internal consistency.

Glycemic Control.—Glycemic control was assessed via A1C, a standard measure that reflects an individual's average blood glucose level over the last two to three months. Higher A1C values indicate worse glycemic control. All A1C tests were conducted by Quest Diagnostics laboratories (West Hills, CA), which adheres to guidelines set forth by the College of American Pathologists.

Statistical Analyses

Data analysis was performed using IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY: IBM Corporation) and Hierarchical Linear and Nonlinear Modeling software (HLM7; Scientific Software International, Lincolnwood, IL). Descriptive statistics were obtained and distributions were examined for normality. No outcome variables exhibited significant deviations from normality requiring transformation.

Mixed models tested a three-way interaction effect Distress (analyzed continuously) × Group (Dulce Digital versus Usual Care) × Time (specified as months between assessments) to determine whether baseline levels of DD prospectively moderated the effect of Dulce Digital (versus usual care) on A1C over time. As a follow-up to this moderation analysis, sub-analyses were conducted using the recommended cut-off for "moderate or high" (DDS ≥2; n=75) versus "no or low" DD (DDS<2; n=51).[25] Specifically, within each of the two distress groups, a two-way interaction effect (Group × Time) evaluated the effect of the Dulce Digital intervention (versus usual care) on A1C separately for individuals who reported moderate/high versus no/low levels of DD at baseline. Exploratory analyses tested a

two-way interaction effect (Group × Time) to examine the effect of Dulce Digital on DD over time. All analyses controlled for age and sex.

Results

Descriptive Statistics

The average age of participants was 48.43 years (SD = 9.80); the majority was female (75%), born in Mexico (91%), uninsured (75%), and reported less than a ninth-grade education level (73%). At baseline, average A1C was 9.5% (80 mmol/mol), SD = 1.3, and average fasting plasma glucose was 187.17 mg/dL, SD = 64.75. There were no statistically significant differences between moderate/high and no/low distress groups on demographic or clinical variables at baseline (*p*s > .05).

Moderation Analyses

A statistically significant three-way interaction effect (Distress × Group × Time) indicated that baseline levels of DD prospectively moderated the effect of Dulce Digital on glycemic control over time ($p = .001$). Follow-up sub-group analyses revealed a significant Group × Time interaction effect in the moderate/high DD group ($B = -.17$, $p < .001$), but not in the no/low distress group ($B = .04$, $p = 0.65$). This finding suggests that the overall effect of the Dulce Digital intervention (compared with usual care) on glycemic control was maintained in the moderate/high DD group, but not in the no/low distress group (see Figure 1). Within the Dulce Digital group, individuals reporting moderate/high DD at baseline achieved larger six-month A1C decreases (Δ−1.23%) in response to the intervention than those experiencing no/low distress (Δ−0.69%). Sensitivity analyses showed no substantive differences in findings when sub-analyses were repeated using a median-split (as opposed to DDS < 2 and ≥ 2) to produce equivalent sub-sample sizes.

Exploratory Analyses

A non-significant two-way interaction effect (Group × Time) indicated that the Dulce Digital and usual care groups did not exhibit differential change over time in DD ($p = .86$). In fact, within group analyses indicated that both groups achieved statistically significant (and roughly equivalent) reductions in distress levels over the six-month intervention period (both *p*s < .001; see Table 2).

Discussion

Despite the pervasiveness of DD[7] and its known impact on diabetes self-management,[9] little is known about the impact of DD on the effectiveness of DSME/S programs - especially in underserved, ethnic/racial minority groups. This study sought to address this gap in the literature by examining whether the effect of an mHealth-based DSME/S intervention (Dulce Digital) on glycemic control varied by baseline levels of DD in underserved, Hispanic adults with poorly controlled T2DM. Findings indicated that DD moderated the effect of Dulce Digital (versus usual care) on changes in glycemic control over time. However, contrary to hypotheses, increases in DD appeared to *augment* intervention effectiveness. Specifically, participants within the Dulce Digital group who had moderate/

high distress at baseline showed a 1.78 times larger decrease in A1C over time compared to those with no/low distress.

This finding is surprising given that, overall, research has found DD to be associated with *poorer* outcomes.[9] It is also inconsistent with a study that found DD to predict *reduced* engagement with an internet-based diabetes care management program.[26] It is important to note that the differential A1C improvements across distress groups cannot be explained by worse glycemic control (i.e., "more room for improvement") in the moderate/high distress group at baseline; there was no significant difference in starting A1Cs between the moderate/high and no/low distress groups (9.5% vs. 9.6%, respectively, $p = .71$). Clearly, further research is needed to investigate the mechanism underlying the relationship observed in the present study. However, one possibility is that an "optimal" level of distress exists; meaning, feelings of DD actually increase motivation or engagement when DD levels fall within a certain range. DD levels that are too high may hinder patient engagement while levels that are too low may not provide enough incentive to change. We were unable to explore this concept directly due to the fact that the majority (70%) of DDS scores fell below 3 (out of a possible 6). Future studies should consider expanding the reach of interventions to patients with greater distress, perhaps by employing targeted and/or more intensive recruitment efforts (e.g., stratified enrollment by DDS scores) to ensure that the full continuum of DD is represented in the sample. Another possible explanation for the observed findings is that the digital delivery of this DSME/S intervention helped to circumvent the stress or burden that can be encountered with traditional face-to-face visits (e.g., travel, specified appointment times). For individuals who have difficulty accessing DSME/S services due to practical barriers, the burden of attending weekly education sessions may increase DD and limit the effectiveness of those programs. Additionally, more distressed individuals may find the ongoing delivery of self-management content in small doses, with medical assistant contact as needed, to be more helpful than the traditional format of longer classes delivered over a circumscribed period of time. While additional research is required to confirm, it is possible that the ease of accessibility and feasibility inherent to a mHealth intervention may allow individuals experiencing distress to engage more effectively. Future research is needed to examine if the observed moderating effect of DD on program effectiveness generalizes across DSME/S delivery modes (traditional vs. digital).

While the purpose of the parent paper (i.e., Fortmann et al., 2017[18]) was to investigate the effectiveness of Dulce Digital in improving glycemic control, the purpose of the current study was to examine whether baseline levels of DD impacted clinical benefit from Dulce Digital. This secondary analysis offers unique insight into how baseline levels of DD levels prospectively moderate intervention effects on A1C; however, these results should be understood in the context of several limitations. First, this study was not designed to evaluate the impact of DSME/S on DD (e.g., participants were not required to have elevated DD) and was not statistically powered to test mediation, or whether intervention effects on distress, in turn, led to changes in A1C. The finding that DD mediates the effect of DSME/S on A1C has been observed in some (e.g.,[27]) but not all prior studies (e.g.,[28]). However, given that reductions in DD over time were equivalent across Dulce Digital and usual care groups, it is unlikely that Dulce Digital's impact on distress would explain the differential reductions in

A1C. Second, as reported in the primary outcomes paper, while the overall attrition rate was similar to those observed in previous research,[29] attrition was slightly higher in the intervention (15.87%) versus usual care group (4.67%). Therefore, those who remained in the study through month-6 may have been more motivated and engaged in the program. However, neither DD scores at baseline nor any sociodemographic factor differed significantly between drop-outs and completers (*p*s>.05), and all analyses were conducted using an intent-to-treat approach. A third limitation is that in order to conduct the current sub analyses, the sample was divided into two groups, consequentially reducing sample size. The significant findings related to clinical[18] and psychosocial outcomes warrant the replication of similar programs with larger sample sizes in the future. Finally, because the majority of participants in this study did not report extremely high levels of distress, it is possible that patients with higher scores may not have been reached by recruitment staff, and/or systematically opted out of the study. Because DD was not routinely captured as part of study screening or routine clinic procedures, we are unable to investigate the distress scores among those who enrolled versus opted out, did not qualify, or could not be reached.

Despite these lingering questions, the results of the current study have important applications to the practice of diabetes education. The results support the ADA's recommendation to refer patients exhibiting symptoms of DD to DSME/S as a first step, given the significant improvements in clinical outcomes achieved over the course of the intervention. The results also suggest that a reduction in DD may not be linked to improvement in clinical outcomes – i.e., both the Dulce Digital and Usual Care groups in this study achieved a similar reduction in distress at 6 months, yet only the Dulce Digital group achieved a significant reduction in A1C. As noted above, further research is needed to better understand the relationship and various pathways between DD and glycemic control. However, the finding that reductions in A1C did not appear to correspond to reductions in DD is encouraging for both diabetes educators and patients given the often enduring nature of DD. Additionally, these findings suggest that on-going DSME/S content delivered remotely in smaller doses may be even more effective for certain emotional distress profiles. Therefore, including DD as a consideration when selecting treatment approach may be worthwhile. Future research is needed to fully understand how and why individuals experiencing greater DD exhibited larger A1C improvements than those with less distress – and in particular, if this relationship persists across the distress continuum, in other sociodemographic groups, and across both mHealth and live/traditional DSME/S programs.

Acknowledgments:

This research would not have been possible without the research coordination provided by Magdalena Hernandez and clinical research coordinator Maria Isabel Garcia, RN, MSN of the Scripps Whittier Diabetes Institute. The authors thank the staff and participants of the Dulce Digital study for their important contributions, and the administration and staff at Neighborhood Healthcare for their partnership in this investigation.

Funding: The current research was supported by grant 115M803379 by the McKesson Foundation and support from the Investigator–Initiated Study Program of LifeScan, Inc, providing glucose testing meters and strips for all participants. Additional support was provided to the authors by 5 U54 TR002550-02 (Topol) and 5 P30 DK111022-03 (Walker).

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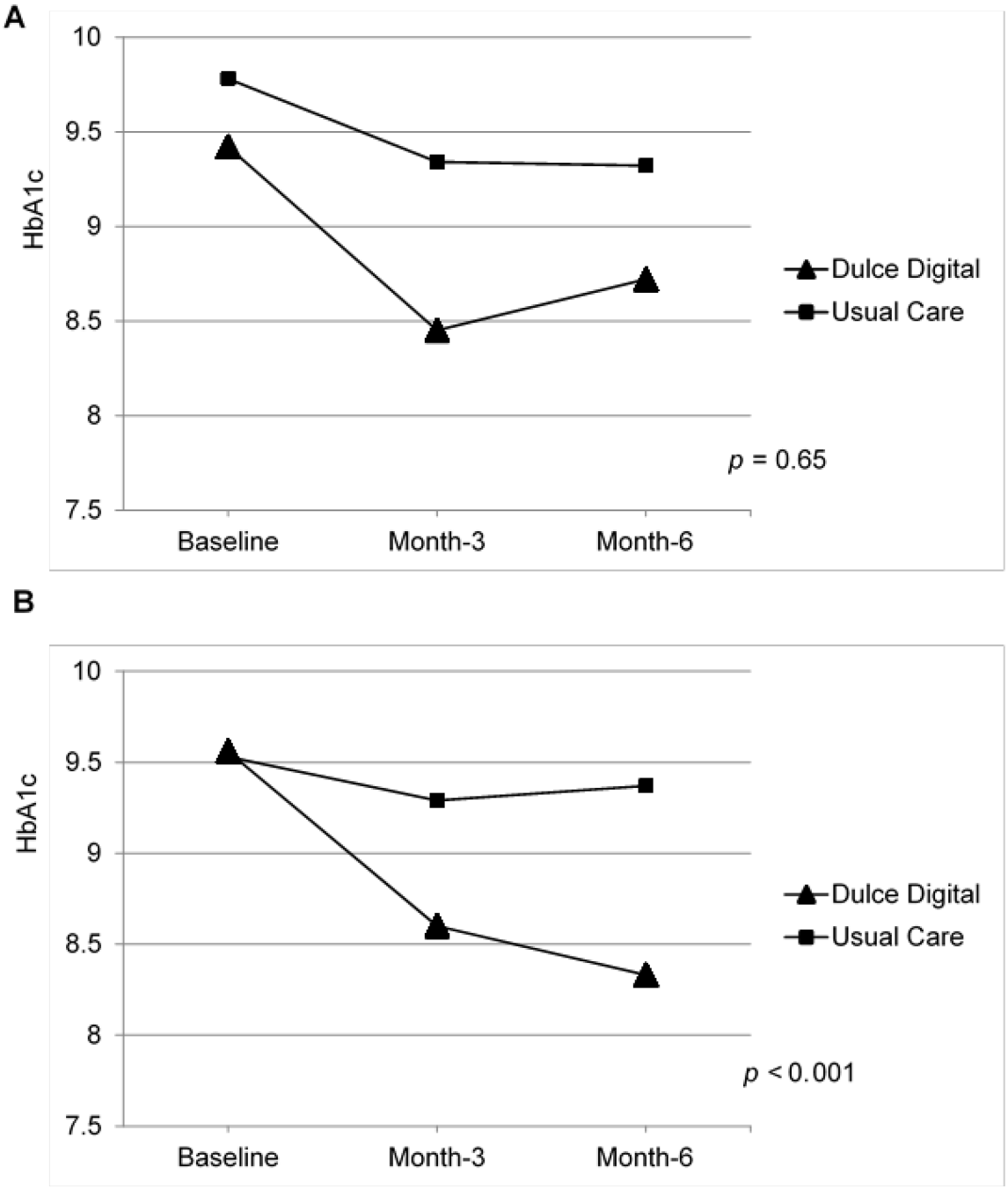

Figure 1.

A1C group means, over time, in the **(A)** no/low distress and **(B)** moderate/high distress sub-groups. *P*-values presented for the Group × Time interaction effect in each sub-group.

Table 1

Baseline Characteristics for the Overall Sample (N = 126)

Characteristic	n (%)
Age in years [mean (SD)]	48.5 (9.8)
Female	94 (75)
Born in Mexico	115 (91)
Spanish as preferred language	116 (92)
Uninsured	95 (75)
Household income <$2,000/month	109 (87)
Married or living with partner	89 (71)

Note. All statistics are n (%) unless otherwise specified.

Table 2.

Change In Mean DD Scores Over Time in the Dulce Digital and Usual Care Groups

	Baseline		Month 3		Month 6		*p*-value
	n	**Mean (SD)**	***n***	**Mean (SD)**	***n***	**Mean (SD)**	
Dulce Digital	63	2.32 (1.32)	50	1.93 (0.92)	50	1.85 (0.93)	< .001
Usual Care	63	2.53 (1.24)	58	2.39 (1.26)	59	2.09 (1.17)	< .001

Note. P-values reflect within-group change over time on DDS.