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Engagement, Adherence, and Clinical Benefit from mHealth Interventions for Latinos with Poorly Controlled Type 2 Diabetes: What Are the Roles of Diabetes Distress and Other Participant Characteristics?

A dissertation submitted in partial satisfaction of the requirements for the degree of Doctor of Philosophy

in

Clinical Psychology

by

Taylor L. Clark

Committee in charge:

University of California San Diego

Professor Niloofar Afari
Professor Thomas Rutledge

San Diego State University

Professor Linda Gallo, Chair
Professor Keith Horvath
Professor Scott Roesch
Professor Gregory Talavera

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The dissertation of Taylor Clark is approved, and it is acceptable in quality and form for publication on microfilm and electronically.

Chair

University of California San Diego

San Diego State University

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The dissertation author was the primary investigator and author of this material.

Vita

Education

2017	Bachelor of Arts in Psychology, San Diego State University
2020	Master of Science in Clinical Psychology, San Diego State University
2024	Doctoral Internship in Clinical Psychology, University of California, San Diego/VA San Diego Internship Program
2024	Doctor of Philosophy in Clinical Psychology, San Diego State University / University of California San Diego Joint Doctoral Program in Clinical Psychology

Fellowships

2018-2022	University Graduate Fellowship, San Diego State University

Publications

1. Bagsic, S. R. S., Savin, K. L., Soriano, E. C., San Diego, E. N., Orendain, N., **Clark, T.L.,** Sandoval, H., Chichmarenko, M., Perez-Ramirez, P., Farcas, E., Godino, J., Gallo, L. C., Philis-Tsimikas, A., & Fortmann, A. L. (in press). Process evaluation of Dulce Digital-Me: An adaptive mHealth intervention for underserved Hispanics with diabetes. *Translational Behavioral Medicine*

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Abstract of the Dissertation

Engagement, Adherence, and Clinical Benefit from mHealth Interventions for Latinos with Poorly Controlled Type 2 Diabetes: What Are the Roles of Diabetes Distress and Other Participant Characteristics?

by

Taylor L. Clark

Doctor of Philosophy in Clinical Psychology

University of California San Diego, 2024

San Diego State University, 2024

Professor Linda Gallo, Chair

Diabetes self-management and support (DSME/S) delivered by mobile health (mHealth) technologies can circumvent access barriers experienced by Hispanic/Latino (hereafter, Latino) individuals with type 2 diabetes (T2D), however, little is known about how participant characteristics and diabetes distress (DD) levels shape engagement with, adherence to, and clinical benefit from these interventions. This 3-paper dissertation aimed to elucidate these questions by examining: (1) the moderating effect of baseline DD on glycosylated hemoglobin A1c (A1c) improvements; (2) associations of participant characteristics and baseline DD with engagement and adherence outcomes; (3) changes in DD over time and relationships between baseline DD and changes in DD with changes in A1c, in the context of two mHealth randomized trials.

Study 1 used data from the Dulce Digital study (N=126), which tested a 24-week long mHealth DSME/S intervention (Dulce Digital) versus Usual Care among Latino adults with poorly managed T2D. A statistically significant three-way interaction effect indicated that participants with moderate/high DD at baseline achieved significantly larger six-month A1c decreases following the intervention than those with no/low DD. **Study 2** used data from the Dulce Digital-Me randomized comparative effectiveness trial (N=310), which enrolled Latino adults with poorly managed T2D to static or adaptive (automated vs. telephonic) versions of Dulce Digital. Older age, longer diabetes duration, limited health literacy, and greater baseline DD were significantly associated with completion of fewer ecological momentary assessments, while preference for Spanish over English language was associated with higher completion rates of health coaching calls. **Study 3** used data from the Dulce Digital-Me trial and found that DD significantly decreased over the intervention period. Higher baseline DD was linearly associated with higher A1c post-intervention. A lack of significant person-level variability in changes in DD over time precluded examination of the association with changes in A1c.

Findings highlight the value of mHealth interventions for Latino adults with T2D and also clarify for whom these mHealth approaches may be most appropriate. Directions for future research include further elucidation of the role of DD in A1c change, and testing adaptions (e.g., added psychosocial support) to current mHealth approaches to further enhance clinical, psychosocial, and engagement outcomes.

1. Introduction

Type 2 diabetes is a chronic metabolic disorder that affects nearly 27 million Americans and is the 7th leading cause of death in the United States (1, 2). Experts predict that diabetes cases will increase more than 50% and deaths attributable to diabetes will increase nearly 40% by the year 2030 (3). Nearly 1 in 6 U.S. adults are expected to be diagnosed with this condition by 2060 (4). The rapid increase in diabetes prevalence will not only affect the lives of patients and their families but will continue to impose substantial economic burden on society, incurring billions of dollars each year in direct medical costs and lost productivity in the U.S. (5, 6).

Importantly, the burden of diabetes is not evenly distributed among sociodemographic groups in the U.S. and significant disparities have been observed. Racial and ethnic minority communities (e.g., Hispanic/Latino/a/x/e; hereafter "Latino") are disproportionately affected by diabetes due to a variety of biological, clinical, social, and health system factors (7-10). The multi-site Hispanic Community Health Study/Study of Latinos found an overall diabetes prevalence of 16.9% in 16,145 adults from four metropolitan areas in the U.S., notably higher than the diabetes prevalence rate of 10% among White adults (11). Not only do Latinos experience diabetes at a higher rate than their White counterparts, but they also exhibit poorer clinical management and worse outcomes once diagnosed (12, 13). Prior studies have observed less engagement in diabetes self-management behaviors (e.g., healthy eating, physical activity), poorer glucose control, and higher incidence of microvascular complications among this group (8, 14-17). Thus, developing interventions tailored for Latinos and their unique sociocultural context and understanding factors related to engagement in, adherence to, and benefit from these interventions are urgent public health goals.

Characterizing Type 2 Diabetes

Type 2 diabetes (T2D) is characterized by insulin deficiency as a result of pancreatic beta-cell dysfunction and insulin resistance, causing high levels of blood glucose, or hyperglycemia. Chronic hyperglycemia and other metabolic aberrations in diabetes can lead to the development of microvascular (e.g., retinopathy and blindness, neuropathy, nephropathy) and macrovascular (e.g., heart disease, stroke, peripheral artery disease) complications. Achieving and maintaining good glycemic control, along with reducing other risk factors like obesity, hypertension, hyperlipidemia, and smoking, can delay the onset and progression of these complications (18, 19).

Glycosylated hemoglobin A1c (A1c) is a blood test that measures average blood sugar levels over the past three months and is used as a primary indicator of clinical control in diabetes. Prior research has found that A1c levels <7% produce significant reductions in incidence of diabetes-related complications and mortality (18-21). Thus, A1c <7% is recommended by the American Diabetes Association as an ideal target for most adults with diabetes (22). Achieving this target often involves the use of pharmacological interventions and lifestyle modification. Suggested behavior changes include adopting a healthier diet low in sugar and unhealthy carbohydrates, increasing physical activity levels, taking medications/insulin as prescribed, monitoring blood sugar and blood pressure, reducing stress, and maintaining good emotional health (23).

Characterizing Diabetes Distress

Research exploring the patient perspective of diabetes has identified that patients often find these behavior changes to be very time-intensive, burdensome, expensive, and difficult to initiate and maintain (24, 25). The concept of ‘diabetes distress’ was first introduced in 1995 and encapsulates the feelings of frustration, guilt, defeat, and overwhelm that often arise for individuals managing this complex, demanding disease (26). A 2017 systematic review and meta-analysis of 55 studies (N=36,998) found that 1 in 3 adults with diabetes endorsed moderate to high levels of diabetes distress (27). Limited evidence also suggests that diabetes distress is more prevalent among Latino adults with diabetes compared to their non-Hispanic White counterparts (28). Studies comparing diabetes distress and depression have found that not only is diabetes distress more common among adults living with diabetes, but it is also more strongly and consistently associated with poorer diabetes self-management and is moderately associated suboptimal clinical control (29-33).

Diabetes Self-Management Education and Support (DSME/S)

The American Diabetes Association's (ADA) position statement on psychosocial care for diabetes recommends that care teams routinely monitor diabetes distress using validated measures and refer patients exhibiting significant levels of distress to diabetes self-management education and support (DSME/S) (34). DSME/S, which is traditionally delivered in a face-to-face setting, is an accredited service that presents an evidence-based curriculum covering medication adherence, healthy eating, physical activity, self-monitoring, risk reduction, and healthy coping (35). According to the Centers for Disease Control and Prevention (CDC), DSME/S classes often take place in hospital outpatient departments, independent clinics (including Federally Qualified Health Centers), and even pharmacies (36). Per the ADA's psychosocial position statement, the purpose of the DSME/S referral is to provide patients exhibiting significant diabetes distress with the opportunity to "address areas of diabetes self-care that are most relevant to the patient and have the most impact on diabetes outcomes" (p. 213211; (34)). A systematic review exploring the biological, psychological, and social benefits of DSME/S found that not only did DSME/S interventions improve diabetes outcomes (e.g., A1c), they also significantly reduced distress and anxiety (37). Another systematic review examined whether DSME/S was effective at reducing health-related emotional distress among *Latino* adults with diabetes (38). This review identified a lack of methodologically robust studies that included predominantly Latino samples; however, of the studies that were identified, most (70%) reported a significant reduction in diabetes distress after participating in DSME/S with effect sizes ranging from -0.17 to -3.85 (38).

While there is some evidence that DSME/S can improve distress, utilization of traditional, face-to-face DSME/S is low (<5% of adults with diagnosed diabetes; (39)). This is especially true for Latino adults, who experience practical (work/caregiving conflict, lack of transportation) and healthcare access barriers at a higher rate than White adults with diabetes (40, 41). In fact, prior research has found that most DSME/S attendees tend to be White and English-speaking (40). Given the higher prevalence of diabetes, poor diabetes outcomes, and diabetes distress among Latinos, developing interventions that address cultural factors that influence diabetes management and are accessible to this high-risk group are paramount to reducing health disparities.

One way in which interventions have become more accessible is by use of mobile health technologies. Mobile health (mHealth) is a general term that encompasses use of mobile phones and other wireless technologies in medical care and has been used to improve health outcomes in a variety of diabetes (42) and other chronic disease interventions (43, 44). Despite the rapid advancement of mHealth technologies, only a few mHealth diabetes interventions have been conducted in predominantly Latino samples (45). Importantly, this is not due to lack of mobile technology access among this group. Cell phone ownership is very high and roughly equivalent between Latinos and non-Hispanic whites and Latinos are more likely than White adults (73% vs. 58%) to use their mobile phone to seek out health information (46, 47). Results from preliminary mHealth studies indicate that delivering DSME/S using mobile technologies can extend the reach of care to Latinos and can be an effective way to improve A1c (48). However, what remains unknown is if/how participant characteristics, including levels of emotional distress like diabetes distress, impact how patients engage with, adhere to, and benefit from mHealth DSME/S programs. This information could help elucidate if and when a mHealth DSME/S treatment approach might be most appropriate for a patient with poorly controlled T2D.

Predictors of Engagement in and Benefit From mHealth DSME/S

User engagement and adherence are crucial to the success of any intervention, but particularly those that utilize mHealth modalities. While a notable advantage of mHealth is the ability of participants to receive intervention content remotely and in the context of their daily lives, these benefits may be nullified if participants are not actively engaged and attending to this content. There is greater potential for this to happen when content is passively delivered (e.g., by text message) as opposed to delivered in the traditional, face-to-face setting. Despite the importance of engagement in mHealth studies, a 2016 systematic review exploring patterns of engagement in mobile and web-delivered self-management interventions among adults with T2D found that engagement is not often reported (49). However, of the studies that did report user engagement, older age, being non-White, and lower health literacy were identified as important predictors of *less* engagement in digital interventions which in turn predicted poorer clinical outcomes (49). To-date, only one study has examined participant characteristics and mHealth engagement in a predominantly ethnic or racial minority sample and found that Black race was significantly associated with less engagement while age, education, income, sex, health literacy, and diabetes duration were not (50). The research examining diabetes distress as a predictor of engagement, particularly among Latinos, is sparse, even though diabetes distress seems to be related to behavior (31, 33, 51). Fonda et al. explored whether engagement in an internet-based diabetes care management program, which included some elements of DSME/S but had a primary focus on care management by a nurse practitioner, was predicted by diabetes distress at baseline. Results indicated that higher distress predicted less engagement in the intervention within this predominantly White sample (52). No other studies to-date have expanded these findings to mHealth DSME/S or Latinos specifically. Overall, results have been mixed and gaps in the literature remain.

Diabetes distress may also shape who benefits most from DSME/S interventions, including mHealth approaches. Several studies have found that reductions in diabetes distress were significantly related to improvements in A1c following a DSME/S intervention, including among Hispanic and Black adults (30, 53-56). However, other studies that have reported improvements in glycemic control post-DSME/S intervention did *not* observe significant between-group changes in diabetes distress over time (57, 58). These findings suggest that the nature of the relationship between diabetes distress and glycemic control following an intervention may be particularly complex, and that intervention design and the population studied might explain some of these discrepancies. Only one study to-date has specifically examined diabetes distress in the context of a *mHealth* DSME/S intervention designed for Latino adults ("Dulce Digital"; Study 1 in this dissertation) (58). This study reported that baseline levels of diabetes distress moderated the effect of the Dulce Digital intervention, such that participants with moderate to high levels of distress experienced relatively *greater* clinical benefit from the intervention compared to participants with no or low levels of distress. This suggests that baseline levels of diabetes distress might be an important predictor of benefit from mHealth DSME/S and that individuals distressed by their diabetes may actually benefit more from such interventions. A possible explanation for this could be that the low burden nature of mHealth helps to circumvent stress that can be encountered, particularly by Latino adults, with traditional face-to-face visits (e.g., finding transportation, time off work/away from caregiving).

It is also possible that an "optimal" level of diabetes distress exists, for engagement in, adherence to, and benefit from DSME/S interventions. The Yerkes-Dodson law, which posits that an optimal level of arousal or stress exists for performance in the shape of an inverted U-curve, was initially discovered in a laboratory setting with mice, but has since been applied to a variety of settings outside the laboratory in humans (59). Non-linear relationships following this inverted U-shaped curve have been observed when examining optimal levels of noise arousal and learning (60), as well as for anxiety levels and test performance (61). In the context of health behavior change, studies have found that moderate levels of weight dissatisfaction, a stress promoting factor, at baseline result in better weight loss outcomes when compared to low or high levels of baseline weight dissatisfaction (62, 63). It is possible that low levels of arousal or stress may not provide enough incentive to change, whereas extremely high levels of arousal or stress may feel too overwhelming and thus, debilitating. While these examples suggest that optimal levels of stress or arousal for performance exist in multiple areas, this has yet to be formally explored in the context of diabetes distress.

As noted above, preliminary results from Clark et al. (2020) suggest that moderate levels of distress may be optimal, however, further exploration of this was limited by the study's small sample and lack of variability in distress scores (particularly on the higher end of the continuum), as 70% fell below 3 out of a possible 6 (58), indicating low levels of diabetes distress.

Additionally, this study did not investigate the role of diabetes distress as it pertains to engagement in the study. Elucidating the role of diabetes distress, as it relates to engagement with, adherence to, *and* benefit from an mHealth DSME/S intervention has important implications for better understanding how and when to best intervene. If patients with no to low levels of diabetes distress prior to intervention exhibit worse engagement/adherence and poorer outcomes post-intervention, eliciting more motivation through techniques like motivational interviewing may be an important first line of treatment before engaging them in DSME/S. Additionally, patients with high (and debilitating) levels of distress may benefit from evidence-based approaches like acceptance and commitment therapy or cognitive psychotherapy (64, 65) to decrease distress to a more manageable level before participating in DSME/S. Again, better understanding of these relationships is of particular importance in the Latino community, given the higher prevalence rates of both diabetes and diabetes distress among this group.

Summary

Optimal health outcomes in diabetes are better achieved when patients can access DSME/S. As reported, Latino adults with diabetes experience a number of barriers to accessing traditional DSME/S, despite greater need for these services. mHealth provides an opportune pathway for Latinos to get the diabetes education they need. However, engagement is paramount to the success of mHealth interventions and little research has explored if/how various patient characteristics are related to engagement with and adherence to mHealth DSME/S interventions, particularly among Latinos. Diabetes distress may also play an important role in determining how well participants will engage with, adhere to, and clinically benefit from an mHealth intervention. As past models of stress and performance have suggested, there may be an "optimal" level of distress for these outcomes.

Preliminary research from Study 1 in this dissertation suggests that moderate levels of distress may be optimal, yet several limitations precluded further exploration. Thus, the purpose of Studies 2 and 3 in this dissertation are to build upon the findings from Study 1 by examining the relationships between participant characteristics, diabetes distress, engagement/adherence, and improvements in glycemic control using a large dataset of Latino adults with poorly controlled type 2 diabetes enrolled in a mHealth DSME/S intervention. A better understanding of these relationships could have important clinical applications. If a moderate level of distress is optimal for observing better outcomes (in terms of engagement, adherence, and clinical benefit), then addressing distress (either by first increasing a sense of urgency/importance or by decreasing debilitating levels of distress) before engaging participants in mHealth DSME/S might be an important first line of treatment. This dissertation aimed to answer these questions and address remaining gaps in the literature through three papers.

2. Does Diabetes Distress Influence Clinical Response to an mHealth Diabetes Self-Management Education and Support Intervention?

Clark TL, Gallo LC, Euyoque JA, Philis-Tsimikas A, Fortmann AL.

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.

Introduction

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 (66). The International Diabetes Federation projects an approximate 50% increase in diabetes rates by the year 2045 (67). 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 (67). Within the U.S., significant disparities in the prevalence of diabetes have been observed in socioeconomically disadvantaged, racial/ethnic minority populations. Further, Hispanics/Latinos (hereafter "Hispanics") have a higher risk of developing diabetes (66) and also exhibit poorer diabetes control (68) and outcomes (69) compared to non-Hispanic whites.

Emotional distress, including depression and disease-specific distress, have been shown to contribute to poorer outcomes in T2DM (70, 71). 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 (72). Although DD and depression are correlated, studies have identified important distinctions between the two conditions. In addition to being more common (29), DD also appears to have stronger and more consistent associations with poorer diabetes self-care and suboptimal glycemic control than does depression (30, 39).

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 (34). 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 (34)). While DSME/S has been established as a critical component of effective diabetes care, utilization is low (<5% of individuals with diagnosed diabetes; (39)) 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 (41, 73-75). Given the widespread and increasing use of mobile phones in the US (76), 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 (77) and preliminary research has reported the same finding in underserved, minority populations, including Hispanics (78-80).

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 (81). 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 (78). 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 (30), 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 (78). The present analysis is distinct given that DD was not examined (as a moderator or an outcome) in the primary outcomes paper (78).

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 (25)) 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 (82) and has been shown to have good psychometric properties and to relate to self-care behaviors and glycemic control in prior research (83). 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) X Group (Dulce Digital versus Usual Care) X 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).(54) Specifically, within each of the two distress groups, a two-way interaction effect (Group X 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 X 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 were female (75%), born in Mexico (91%), uninsured (75%), and reported less than a ninth-grade education level (73%; See Table 1). 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).

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.

Moderation Analyses

A statistically significant three-way interaction effect (Distress X Group X 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 X 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. 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 X 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).

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.

Discussion

Despite the pervasiveness of DD (72) and its known impact on diabetes self-management (30), 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 (30). It is also inconsistent with a study that found DD to predict *reduced* engagement with an internet-based diabetes care management program (84). 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., (78)) 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., (55)) but not all prior studies (e.g., (85)). 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 (86), 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 (78) 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.

Chapter 2, in full, is a reprint of the material as it appears in The Diabetes Educator. Clark TL, Gallo L, Euyoque JA, Philis-Tsimikas A, Fortmann A. Does Diabetes Distress Influence Clinical Response to an mHealth Diabetes Self-Management Education and Support Intervention? Diabetes Educ. 2020 Jun;46(3):289-296. doi: 10.1177/0145721720913276. Epub 2020 Mar 31. PMID: 32228288; PMCID: PMC8344137. The dissertation author was the primary investigator and author of this paper.

3. Do Participant Characteristics and Diabetes Distress Levels Predict Participant Engagement and Adherence in a mHealth DSME/S Intervention?

Clark TL, Philis-Tsimikas A, Fortmann AL, Roesch SC, Spierling-Bagsic SR, Schultz J, Godino JG, Rutledge T, Afari N, Talavera GA, Horvath KJ, Gallo LC.

Abstract

Objective: This study aimed to investigate participant characteristics and baseline levels of diabetes distress as predictors of engagement and adherence in a mHealth diabetes self-management education and support (DSME/S) intervention among at-risk Latino adults with type 2 diabetes (T2D).

Methods: Data were analyzed from a randomized comparative effectiveness trial (Dulce Digital-Me). Participants (N=310) were Latino adults with T2D and poor clinical control recruited from a Federally Qualified Health Center in San Diego, CA. Multiple linear regression models were used to examine participant characteristics and baseline distress as predictors of engagement and adherence in a mHealth intervention.

Results: Participants were 52.1 (±10.2) years old, 69.7% female, with a mean A1c 9.3% (±1.6) at baseline. Older age, longer duration of diabetes diagnosis, limited health literacy, and higher levels of baseline distress were significantly associated with completion of fewer ecological momentary assessment items (all p's $< .05$). Preference for Spanish over English language was associated with higher completion rates of health coaching calls ($p < .05$). There were no significant associations found between participant characteristics or baseline distress with blood glucose monitoring or pillbox openings.

Conclusions: This study highlights demographic and psychosocial factors influencing engagement and adherence in mHealth DSME/S interventions among Latino adults with T2D. Tailored approaches are needed to address barriers to engagement and adherence, particularly among older adults, those with limited health literacy, and those experiencing higher levels of distress. Addressing these barriers and leveraging cultural strengths may enhance engagement, support, and potentially improve health outcomes in this medically vulnerable population.

Introduction

Type 2 diabetes (T2D) is an escalating public health concern affecting nearly 29 million adults in the United States (87-89). Minoritized racial and ethnic communities, including Hispanic/Latino/Latinx (hereafter, "Latino") populations, bear a disproportionately high burden of T2D compared to their non-Hispanic White counterparts (87, 89, 90). Latino populations exhibit poorer clinical management and outcomes following diabetes diagnosis (68, 90-92), and some evidence suggests they may also experience diabetes distress (i.e., the emotional toll of diabetes) at a higher rate (28). Diabetes self-management education and support (DSME/S) is an essential component of effective diabetes care and is the first-line recommendation for patients experiencing significant levels of diabetes distress (34). A recent systematic review illustrated that DSME/S has a positive impact on a variety of biological, psychological, and social outcomes, including A1c and distress (37). Research efforts have been made to tailor DSME/S content to Latino populations and have been met with success in achieving reduced hemoglobin A1c (A1c) (48, 93). A systematic review exploring the effect of DSME/S on diabetes distress among Latino adults specifically, found that 70% of studies observed a significant reduction in diabetes distress, though there was a notable lack of methodologically rigorous studies tested in this population (38).

While DSME/S has been shown to be helpful for Latino populations, it can be difficult to access in traditional, face-to-face formats due to transportation, caregiving, and insurance or cost-related barriers (40, 41, 75). Mobile health (mHealth) approaches have transformed diabetes education delivery for underserved communities by enabling widespread dissemination with greater ease and accessibility (94). Preliminary evidence indicates that mHealth approaches can extend the reach of care to Latino groups and improve glycemic management (48, 78). However, user engagement in mHealth studies is critical, given the passive nature in which mHealth content is often delivered (such as by text message), and the research exploring predictors of engagement in these interventions, especially among Latinos, is limited (49).

A prior systematic review reported that in the few mHealth DSME/S studies that examined predictors of engagement, older age, being non-White, and having lower health literacy were predictors of lower engagement and in turn, poorer clinical outcomes (49). In a study that examined mHealth engagement in a racially and ethnically diverse sample of adults with T2D, Black race was significantly associated with less engagement, while age, education, income, sex, health literacy, and diabetes duration were not (50). There is very limited research examining diabetes distress as a predictor of engagement in mHealth DSME/S, even though diabetes distress has been repeatedly linked to behavior in other studies (31, 33, 51). In a prior study we found that contrary to initial hypotheses, Latino participants with *higher* levels of diabetes distress at baseline exhibited greater improvements in A1c following a mHealth DSME/S intervention relative to participants with no or low distress (58). We hypothesized that there may be an “optimal” level of diabetes distress that facilitates better outcomes. Specifically, drawing from the Yerkes-Dodson law’s U-shaped curve of optimal arousal/stress and performance (59), studies across various domains, including health behavior change, suggest that moderate levels of stress-promoting factors at baseline (e.g., weight dissatisfaction) may promote better outcomes (e.g., greater weight loss) following an intervention, compared to low or high levels of the stress promoting factor (61-63). In the context of mHealth, this phenomenon is potentially applicable to diabetes distress and engagement with mHealth components (e.g., completing text-message based assessments and coaching calls), as well as adherence to diabetes self-management tasks (e.g., checking BG, taking medication). However, this has not yet been explored in this context. Investigating how demographic characteristics and distress levels impact engagement and adherence is important for advancing our understanding of the populations for whom these programs are most effective. This insight can also inform future research endeavors aimed at refining mHealth programs for those who have shown low engagement and adherence.

The current study aimed to address these gaps by examining participant characteristics (age, sex, education, income, language preference (English or Spanish), diabetes duration, and health literacy; Aim One) and baseline levels of diabetes distress (Aim Two) as predictors of engagement and adherence in interventions delivered in a randomized trial ("Dulce Digital-Me"), which tested mHealth DSME/S interventions for Latinos with T2D. Given prior research indicating that moderate levels of stress can be related to better outcomes, baseline diabetes distress was examined as both a linear and quadratic term to assess the presence of a curvilinear relationship. We hypothesized that older age and lower levels of health literacy would be related to less engagement and adherence in the intervention based on prior research. We also hypothesized a curvilinear relationship between baseline diabetes distress and our engagement and adherence outcomes, such that low and high levels of distress, relative to moderate levels, would be related to less engagement and adherence. Low, moderate, and high levels of distress were defined using predetermined scale cut-offs (54). Analyses were largely exploratory, given the limited research to date.

Methods

The research protocol was approved by the Institutional Review Boards of Scripps Health (reviewing IRB) and San Diego State University (reliant IRB). All participants provided written informed consent. A full description of Dulce Digital-Me ("parent study") methods have been previously published and is briefly summarized below (95).

Participants and Setting

Data from N=310 participants were collected as part of a randomized, parallel-groups, comparative effectiveness trial (Dulce Digital-Me) conducted from October 2017 to February 2020. The target population for this study included Latino adults (ages 18 years or older) who were registered patients of a Federally Qualified Health Center (FQHC) partner in San Diego, California which serves a predominantly Latino, Mexican heritage, Spanish-speaking, immigrant population. Eligibility criteria included a diagnosis of T2D and at least one of the following within 90 days of enrollment: A1c ≥ 8.0%; SBP ≥ 140 mm/Hg; LDL-C ≥ 100 mg/dL. Exclusion criteria were severe illness precluding regular clinic visits (e.g., serious malignancy; end stage liver or kidney disease; severe cognitive impairment); pregnant or lactating; type 1 or gestational diabetes; lack of minimal literacy needed to participate in the text intervention; severe auditory or visual problems; primary language other than Spanish or English; not willing to carry a mobile phone; plans to relocate. The analytic sample for the current study included all participants of the parent study, Dulce Digital-Me. In Aim Two analyses, our sample was restricted to participants who completed the Diabetes Distress Scale-17 (DDS-17) at baseline (n=307; (25)).

Study Design and Procedures

Recruitment. Participants were identified using automated, electronic health record (EHR)-derived patient identification reports that were generated in collaboration with the FQHC system partner. Eligible and interested patients were invited to an initial visit, where the study was fully described, written informed consent was obtained, and baseline assessments were performed. During this visit, participants were also given their study-provided devices with thorough instructions and training on how to use them during their 6 months in the study.

Study Devices. All participants received a wireless-enabled glucometer, medication adherence pillbox, and a cell phone (unless they preferred to use their personal cell phone). The glucometer automatically transmitted blood glucose (BG) values in real-time via cellular connectivity to a secure and scalable platform that made participant device data available to study staff for safety purposes. Participants were also provided with and instructed to use a wireless-enabled pillbox to manage their anti-hyperglycemic agent(s) or cholesterol medications. Each time the dispenser was opened, the pillbox transmitted a time-stamped event record to the data aggregation platform.

Intervention Groups. Participants were randomized into one of three intervention groups during the initial visit using 1:1:1 equal allocation: Dulce Digital (DD), Dulce Digital-Me-Automated (DD-Me-Auto), or Dulce Digital-Me-Telephonic (DD-Me-Tel). All participants, irrespective of group, continued to receive evidence-based diabetes care at the clinic for the duration of the study.

<u>Dulce Digital (DD).</u> Participants in the DD group received core text messaging content informed by the Association of Diabetes Education and Care's seven essential self-care (AADE-

7) behaviors for diabetes and current best practices in evidence-based behavior change approaches (95, 96). An earlier version of DD was shown to be effective in reducing A1c relative to Usual Care in a similar population (78). The culturally and health literacy-appropriate text messages were adapted from this original pilot study and covered the following domains: Medication adherence, clinical indicators, dietary behaviors, physical activity, and stress/emotional distress. DD participants in the current study also received prompts to check their BG levels using the glucometer, to manage medications using their pillbox, and to respond to ecological momentary assessment queries delivered by text message. DD participants did not receive tailored goal setting or feedback in response to their text messages, remote BG, and remote medication adherence data.

Dulce Digital-Me-Automatic (DD-Me-Auto). The DD-Me-Auto group received all the DD components described plus adaptive, automated behavioral feedback and goal setting in response to their transmitted BG values, medication adherence, and ecological momentary assessment (EMA) data, as well as the ability to select the order of core content domains. All messages were tailored to reinforce participants' unique, self-reported progress on each behavioral domain.

DD-Me-Telephonic (DD-Me-Tel). Those in the DD-Me-Tel group received all DD components described above plus adaptive feedback and goal setting from a health coach instead of algorithm-driven automated messaging. These participants received weekly calls from the health coach to discuss their study progress and receive support and feedback. This coach was a bilingual, trained medical assistant with lived experience with T2D. Additional details about qualifications and training are provided in the research protocol (95).

Importantly, in the parent study, all three groups received active intervention and were predicted to show clinical benefit; the adaptive groups (DD-Me-Auto and DD-Me-Tel) were hypothesized to show greater benefit than the DD group, but all groups were predicted to show clinically significant improvement in A1c levels (i.e., at least a 0.5% reduction; (95)). The current study aimed to examine how participant characteristics and diabetes distress related to engagement and adherence in Dulce Digital-Me, irrespective of group. Thus, intervention group was included as a covariate in all models, as described below in the 'Statistical Analyses' sections.

The primary outcomes paper reporting group-based differences on primary and secondary outcomes is currently under review and will be published elsewhere. In brief, we observed statistically significant improvements in A1c from baseline to month 6 (meanΔ per month = -0.17, 95% CI [-0.20, -0.14]; $p < 0.001$), with no significant group differences observed across time. However, the adaptive groups (DD-Me-Auto and DD-Me-Tel) showed greater improvements in some areas of self-management behaviors compared to the static DD group (Philis-Tsimikas et al., 2024, under review).

Measures

Participant Characteristics. Demographic information including age, sex, education, income, language, and duration of diabetes diagnosis was captured at the baseline visit during survey administration. Health literacy was assessed at baseline using validated English and Spanish versions of the Single Item Literacy Screener [SILS; (97)]. All assessment and intervention activities were conducted in the patient's preferred language (English or Spanish).

Diabetes Distress. Diabetes distress was measured using the 17-item Diabetes Distress Scale (DDS-17) in each participant's preferred language, English or Spanish, during the baseline recruitment visit and the 6-month follow-up assessment. Respondents self-reported the extent to which they had experienced distress across four domains including emotional burden, physician-related distress, regimen distress, and diabetes-related interpersonal distress over the past 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 DDS total score for each participant, with higher scores indicating greater levels of distress (DDS total score possible range =1.0 - 6.0). The cut point for clinically meaningful distress has been previously established as ≥2.0 (54), with scores from 2.0-2.9 indicating moderate distress, and scores ≥3.0 indicating high distress. The DDS-17 has been translated into Spanish (98) and has been shown to have good psychometric properties and to relate to self-care behaviors and glycemic control in prior research (25). In this sample, the DDS-17 demonstrated high levels of internal consistency ($\alpha = 0.93$).

Intervention Engagement and Adherence. We assessed participants' engagement and adherence in the intervention by examining engagement with study-specific mHealth components, including (1) The percentage of EMA items completed (EMA completion rate) and (2) The percentage of scheduled health coach calls completed (for those in the DD-Me-Tel group only; coaching call completion rate), as well as adherence to diabetes self-management behaviors, including (3) The percentage of expected pillbox openings completed (pillbox opening rate) and (4) The percentage of expected blood glucose readings completed (BG completion rate). Participants from all groups were sent and asked to respond to a total of 72 EMA questions (3/week for 24 weeks). EMA formatting varied across the 6-month intervention but sometimes required a numeric response (e.g., Likert scale from 1-6) and other times required a yes/no response. Participants in the DD-Me-Tel group were contacted once per week for 24 weeks and had the potential to complete up to 24 calls in total. Any missed calls were rescheduled within the same week as often as possible. The number of pillbox openings expected to be completed was 168 (at least 1 opening/day for 24 weeks). The number of BG readings participants were expected to complete varied by participant based on their baseline A1c, thus the denominator comprising BG completion rate was unique to each participant (see Table 3). A full description of the intervention is available (95).

Table 3. *Expected Counts for Engagement/Adherence Outcomes*

Number of expected EMA responses	72 (3x/week for 24 weeks)			
Number of expected coaching calls (DD-Me-Tel only)	24 (1x/week for 24 weeks)			
Number of expected Wisepill openings	168 (7x/week for 24 weeks)			
Number of expected BG readings (by A1c)	Baseline A1c			
	< 7%	7-8.4%	8.5 – 10%	>10%
Per week	6	9	12	14
Across all 24 weeks	144	216	288	336

Covariates. All analyses controlled for intervention group and baseline A1c. A1c was collected at FQHC laboratory visits following an 8-12 hour fast at baseline. Labs were processed by Quest Diagnostics Inc., which adheres to all guidelines set forth by the College of American Pathologists and National Glycohemoglobin Standardization Program; A1c is assayed by Immunoturbidimetry [Integra 800 Roche; (95)].

Statistical Analysis

All analyses were performed using SPSS (IBM Corporation 1989, 2016). To determine statistical significance, an alpha level of $p < .05$ (two-tailed) was used for all models. Betas were used as an indicator of effect size, with $\beta = 0.1$ indicative of a small effect size, 0.3 = medium, and 0.5 = large (99).

To assess Aim One, separate multiple linear regression models were used to regress each indicator of engagement and adherence (EMA completion rate, coaching call completion rate, pillbox opening rate, BG completion rate; tested as outcomes in separate models), on participant characteristics entered simultaneously (age, sex, education, income, language, diabetes duration, health literacy), while controlling for intervention group and baseline A1c. All four outcomes were modeled continuously, as well as age, diabetes duration, health literacy, and baseline A1c. Categorical variables were coded as follows: Sex (reference category=female), education (reference category=less than high school), income (reference category=$20,000 annually or less), language preference (reference category=English), and intervention group (reference category=DD).

To assess Aim Two, hierarchical comparisons of multiple linear regression models that added the linear effect of diabetes distress, followed by models that added both linear and quadratic effects of diabetes distress were examined. This process was repeated for each of the four outcomes of interest. All analyses controlled for intervention group, and baseline A1c. Models were compared using likelihood ratio tests and effect sizes were quantified in terms of incremental variance (R^2) accounted for between models. For Aim One and Two analyses, cases were excluded using a listwise approach for missing data. Approximately 9% (n=28) of cases were excluded due to non-response to the question assessing income. Income was included as a covariate for all analyses. Missing data rates across all other variables were low (i.e., $\leq$5%).

Results

Descriptive Statistics

Baseline characteristics are shown in Table 4. Participants were 52.1±10.2 years old and predominantly female (n=216; 69.7%). All participants self-identified as Latino, 90.6% (n=281) were born in Mexico, and 93.2% (n=289) endorsed Spanish as their preferred language. The majority of participants had less than a high school education (n=230; 74.9%), annual household income <= $20,000 (n=189; 66.5%) and were unemployed (n=168; 54.5%). Health literacy was limited for about half the sample (46.1%; n=143). The average duration of diabetes diagnosis was 10.4 (±8.2) years and mean A1c at baseline was 9.3% (±1.6). Across all intervention groups, participants completed an average of 52.1% (±32.8) EMA items, 81.3% (±58.5) pillbox openings, and 49.3% (±38.2) BG readings. Those in the DD-Me-Tel group completed an average of 77.1% (±28.1) of coaching calls. The mean total DDS-17 score for the sample was 2.4 (±0.9) out of a possible 6.0, indicating a clinically meaningful level of diabetes distress at baseline overall. Approximately 58% of the sample had a DDS total score above the cut-off for moderate distress (≥ 2.0), which is significantly higher than the prevalence rate of 36% reported in a prior meta-analysis (27).

Table 4. *Descriptive Statistics for Total Sample (N=310)*

Variable	n (%)
Demographic Variables [a]	
Age (years), M (SD)	52.1 (10.2)
Female	216 (69.7%)
Hispanic/Latino ethnicity	310 (100.0%)
Less than high school education/GED	230 (74.9%)
Yearly household income	
<= $20,000	189 (66.5%)

Table 4 Continued.

Variable	n (%)
>$20,000-$30,000	49 (17.4%)
>$30,000	46 (16.2%)
Employment	
Not employed	168 (54.4%)
Employed (Either part-time or full-time)	141 (45.6%)
Marital status	
Not married or living with partner	107 (34.5%)
Married/Living with partner	203 (65.5%)
Place of birth	
United States	20 (6.5%)
Mexico	281 (90.6%)
Other	9 (2.9%)
Preferred Language	
English	21 (6.8%)
Spanish	289 (93.2%)
Insurance	
Uninsured	158 (51.0%)
Insured (Any)	152 (49.0%)
Health Literacy [b]	
Adequate	167 (53.9%)
Limited	143 (46.1%)

Table 4 Continued.

Variable	n (%)
Clinical Variables	
Duration of diabetes diagnosis, years, M (SD)	10.4 (8.2)
BMI, kg/m^2, M (SD)	32.3 (6.6)
A1c, % M (SD)	9.3% (1.6)
SBP, mm/Hg, M (SD)	122.5 (18.4)
LDL-C, mg/Dl, M (SD)	94.6 (38.3)
Diabetes distress, M (SD) [c]	2.4 (0.9)
Engagement and Adherence Variables	
% Ecological momentary assessments completed, M (SD)	52.1% (32.8)
% Coaching calls completed, M (SD)	77.1% (28.1)
% Pillbox openings completed, M (SD)	81.3% (58.5)
% BG readings completed, M (SD)	49.3% (38.2)

Abbreviations: GED= General Education Development Test; BMI=Body Mass Index.

[a] Sample sizes differ due to missing data for individual variables.

[b] Health literacy was assessed using the Single Item Literacy Scale (SILS; adequate or limited).

[c] Diabetes distress was assessed using the Diabetes Distress Scale-17 (total score). Total scores can range from 1.0 to 6.0, and ≥2.0 has been established as a clinically meaningful cut point for the DDS-17.

Engagement Outcomes

EMA Completion Rate. In Model 1, participant characteristics collectively accounted for a significant proportion of the variance in EMA completion rate (R^2=.23, adjusted R^2=.20, $F(11, 251) = 6.90$, $p < .001$). Upon adding baseline diabetes distress as a predictor (Model 2), the variance explained increased to 26.7% (R^2 change=.03) and the model demonstrated a significant improvement in fit (F(1, 250)=11.69, $p < .001$). A one unit increase in diabetes distress at baseline was associated with a 6.4% reduction in EMA completion rate (B=-6.43, 95% CI [-10.14, -2.73]). Older age (B=-0.66, 95% CI [-1.09, -0.23]), longer duration of diabetes diagnosis (B=-0.66, 95% CI [-1.19, -.13]), and limited health literacy (B=-12.12, 95% CI [-19.69, -4.56]) were significantly related to EMA completion. All effect sizes were of small magnitude ranging from -0.16 to -0.20 (see βs in Table 5). The addition of the diabetes distress quadratic term in Model 3 did not increase the variance explained, improve model fit, or display a statistically significant association with EMA completion rate (all *p*s > .05), suggesting a linear, rather than quadratic, relationship (see Tables 5 and 6).

Coaching Call Completion Rate. Model 1 did not account for a significant proportion of the variance in coaching call completion rate among participants who had been randomized to the DD-Me-Tel group ($p > .05$). However, language was statistically significantly related to coaching call completion rate, such that those who preferred Spanish completed 33.2% more calls than those who preferred English (B=33.20, 95% CI [3.80, 62.60]; Table 5). This association was of medium effect size (β = 0.28). Neither baseline diabetes distress nor its quadratic effect was shown to be significantly related to coaching call completion rate and neither improved variance explained or model fit (all *p*s > .05; Table 6).

Adherence Outcomes

Pillbox Opening Rate. Participant characteristics did not demonstrate statistically significant associations with pillbox opening rate (all *p*s > .05; see Table 5). Moreover, neither baseline diabetes distress nor the quadratic effect of diabetes distress significantly predicted pillbox opening rate or enhanced the model's fit (*p*s > .05; see Table 6).

BG Completion Rate. No participant characteristic showed a statistically significant association with BG completion rate (all *p*s > .05, see Table 5). Baseline diabetes distress did not significantly predict BG completion rate and did not enhance the model's fit (p > .05). Additionally, the inclusion of the quadratic term for diabetes distress was also not statistically significant and did not improve the model as shown in Table 6 (*p*s > .05).

Table 5. *Results of Linear Regression Analysis by Engagement/Adherence Outcome* [a]

			95% CI			
Variable	B	SE	LL	UL	β	p
EMA Completion Rate [b]						
Age	-0.66**	0.22	-1.09	-0.23	-0.20	0.00
Gender	-3.16	4.06	-11.15	4.83	-0.04	0.44
Education (>High School)	0.69	4.88	-8.93	10.30	0.01	0.89
Income ($20,001-$30,000)	-0.90	5.01	-10.76	8.96	-0.01	0.86
Income (>$30,000)	5.17	5.30	-5.26	15.60	0.06	0.33
Language Preference (English)	3.47	8.66	-13.58	20.52	0.02	0.69
Diabetes Duration	-0.66*	0.27	-1.19	-0.13	-0.16	0.02
Health Literacy	-12.12**	3.84	-19.69	-4.56	-0.18	0.00
Intervention Group (DD-Me-Auto)	1.04	4.41	-7.65	9.73	0.02	0.81
Intervention Group (DD-Me-Tel)	13.93	4.40	5.26	22.61	0.20	0.00
Baseline A1c	-4.07	1.19	-6.41	-1.72	-0.20	<.001

Table 5 Continued.

Variable	B	SE	95% CI LL	95% CI UL	β	p
Baseline DDS-17 Total Score	-6.43***	1.88	-10.14	-2.73	-0.19	<.001
Coaching Call Completion Rate						
Age	-0.28	0.43	-1.14	0.58	-0.09	0.52
Gender	3.90	6.80	-9.67	17.46	0.07	0.57
Education (>High School)	3.72	8.50	-13.23	20.66	0.05	0.66
Income ($20,001-$30,000)	-5.41	8.17	-21.69	10.87	-0.08	0.51
Income (>$30,000)	9.41	10.01	-10.55	29.36	0.11	0.35
Language Preference (English)	33.20*	14.75	3.80	62.60	0.28	0.03
Diabetes Duration	0.08	0.52	-0.95	1.11	0.02	0.88
Health Literacy	2.49	6.35	-10.16	15.15	0.04	0.70
Baseline A1c	-5.83	2.06	-9.95	-1.72	-0.34	0.01
Pillbox Opening Rate						
Age	0.19	0.43	-0.67	1.04	0.03	0.67
Gender	-15.85	8.01	-31.62	-0.09	-0.13	0.05
Education (>High School)	-8.06	9.64	-27.04	10.93	-0.06	0.40
Income ($20,001-$30,000)	-1.09	9.84	-20.46	18.29	-0.01	0.91
Income (>$30,000)	16.02	10.46	-4.59	36.63	0.10	0.13
Language Preference (English)	-5.51	17.11	-39.20	28.19	-0.02	0.75
Diabetes Duration	-0.57	0.54	-1.63	0.49	-0.08	0.29

Table 5 Continued.

Variable	B	SE	95% CI LL	95% CI UL	β	p
Health Literacy	1.56	7.53	-13.27	16.39	0.01	0.84
Intervention Group (DD-Me-Auto)	11.05	8.74	-6.15	28.25	0.09	0.21
Intervention Group (DD-Me-Tel)	16.96	8.70	-0.18	34.10	0.14	0.05
Baseline A1c	-3.63	2.35	-8.26	0.99	-0.10	0.12
BG Completion Rate						
Age	0.01	0.25	-0.49	0.51	0.00	0.97
Gender	-0.88	4.69	-10.12	8.35	-0.01	0.85
Education (>High School)	-7.00	5.65	-18.13	4.13	-0.08	0.22
Income ($20,001-$30,000)	-6.88	5.77	-18.24	4.48	-0.07	0.23
Income (>$30,000)	1.47	6.14	-10.62	13.56	0.01	0.81
Language Preference (English)	-12.57	10.04	-32.34	7.19	-0.08	0.21
Diabetes Duration	0.03	0.31	-0.59	0.65	0.01	0.92
Health Literacy	-4.49	4.41	-13.18	4.20	-0.06	0.31
Intervention Group (DD-Me-Auto)	-0.41	5.11	-10.47	9.66	-0.01	0.94
Intervention Group (DD-Me-Tel)	10.91	5.11	0.85	20.96	0.14	0.03
Baseline A1c	-8.68	1.38	-11.39	-5.97	-0.39	<.001

[a] Covariates for all analyses included Intervention Group (DD=reference category) and Baseline A1c

[b] Model 2 results are presented, as this model illustrated better fit than Model 1

*p < 0.05, **p < 0.01, ***p < 0.001

Table 6. *Change Statistics for Models 1-3 by Engagement/Adherence Outcome*

Model	R	R^2	Adj R^2	R^2 Change	F Change	Sig. F Change
EMA Completion Rate						
1	.48	.23	.20	-	-	-
2	.52	.27	.23	.03	11.70	<.001
3	.52	.27	.23	.00	.11	.74
Coaching Call Completion Rate						
1	.44	.20	.10	-	-	-
2	.45	.20	.09	.00	.33	.57
3	.46	.21	.09	.01	1.07	.30
Pillbox Opening Rate						
1	.23	.05	.01	-	-	-
2	.24	.06	.01	.00	.96	.33
3	.25	.07	.02	.01	2.07	.15
BG Completion Rate						
1	.43	.19	.15	-	-	-
2	.44	.19	.15	.00	.25	.62
3	.44	.19	.15	.00	.01	.91

Discussion

The results of the current study elucidate how demographic characteristics and diabetes distress are related to engagement and adherence in a mHealth DSME/S intervention among Latino adults with T2D, a group at higher risk for adverse diabetes outcomes. Notably, we observed that older age, longer duration of diabetes diagnosis, limited health literacy, and higher levels of baseline diabetes distress were significantly associated with lower EMA completion rates, with small effect sizes. Lower EMA completion rates might indicate that people were reading texts less often and potentially receiving less of the DSME/S education and tailored feedback (for those in the adaptive groups) as a result. While age and duration of diabetes diagnosis emerged as distinct predictors in these regression models, additional analyses indicated a significant, moderate correlation between the two variables, suggesting potential overlap in their influence on EMA completion rates. Overall, these results are in line with prior research indicating that older age and limited health literacy are often associated with reduced engagement in technology-based interventions (49, 100, 101). The relationship between older age and lower engagement levels in mHealth could be attributed to various factors unique to older adults, including potential limitations in visual, hearing, and/or mobility capabilities, more limited experience/comfortability with technology, and/or less desire or motivation to use mHealth modalities (100, 101). Moreover, while significant efforts were made to tailor DD-Me intervention content to lower education and health literacy levels, our results underscore the persistent influence of health literacy on mHealth engagement. In line with recommendations made previously, future research might consider addressing age and literacy barriers by utilizing platforms more suitable to varying levels of physical abilities (e.g., tablets with larger screens and keyboards), providing more hands-on training and ongoing technological support, leveraging patients' support networks to encourage mHealth utilization (e.g., kids, grandkids), and incorporating use of plain language and visual content (100, 102, 103).

Additionally, while DSME/S has been shown to help reduce diabetes distress, higher levels of distress at baseline may serve as a barrier to engaging with mHealth DSME/S content. This may be particularly relevant in Latino adults with T2D, who have exhibited higher rates of distress in previous research (28). We also observed this in the current sample, where the proportion of participants with clinically meaningful levels of distress (i.e., DDS-17 $\geq$ 2.0) was substantially higher what has been reported in a prior meta-analysis (58% vs. 36%; (27)). This difference could be attributed to socioeconomic and cultural factors that uniquely affect Latinos with low-income living in the U.S. and are assessed as part of the DDS-17 (e.g., questions about financial concerns, social stigma, and interpersonal challenges affecting T2D management). Importantly though, preliminary evidence suggests that higher rates of baseline distress do not necessarily translate to reduced clinical benefit following a mHealth DSME/S intervention (58). At this time, it is unclear whether diabetes distress *must* be reduced prior to engaging in mHealth DSME/S, or whether confounding factors, like lack of perceived time, underlie both low EMA completion rates and greater diabetes distress. Regardless, given the high rate of clinically meaningful distress observed in this sample, future research should consider testing brief, evidence-based interventions targeting diabetes distress, such as Acceptance and Commitment Therapy (65, 104) or Problem Solving Therapy (105), prior to or simultaneously with DSME/S to see if this enhances engagement, psychosocial well-being, and clinical outcomes in this group.

Results from the current study also revealed an association of medium effect size within the DD-Me-Tel group, such that individuals who preferred Spanish language over English exhibited significantly higher coaching call completion rates. Language has often been used as a proxy for acculturation, suggesting that preference for Spanish over English may reflect stronger connection to Hispanic/Latino culture and values (106, 107). As highlighted within the literature, *personalismo* is a core Latino cultural value that emphasizes the importance of warm, caring, and trusting interpersonal relationships and is associated with better outcomes in the healthcare setting (108-110). While speculative, cultural and linguistic concordance between Spanish-speaking participants and the health coach may have fostered a sense of *personalismo*, thereby motivating these participants to actively engage and complete more calls. This emphasis on interpersonal relationships may also explain why the DD-Me-Tel group had generally better engagement than the DD and DD-Me-Auto groups, as described in the DD-Me process evaluation paper (111). Leveraging this cultural value to increase study engagement is an important consideration for future work in this area.

Surprisingly, we did not observe significant associations between demographic variables, diabetes distress, and other outcome measures like BG completion rate and pillbox opening rate. These particular outcomes capture more objective measures of self-management behaviors, suggesting that while certain demographic characteristics and diabetes distress may influence how people engage with the study (i.e., completing EMA items, answering coaching calls), they had no significant effect on concrete tasks of diabetes self-management. It is also possible that prior experiences with more familiar devices like glucometers and pillboxes minimized the impact of demographic characteristics and diabetes distress on usage frequency. This may have been particularly relevant in the current sample where participants had diabetes for an average of ten years before enrollment in the study. Overall, these findings are contrary to prior literature, which has often concluded that diabetes distress negatively affects engagement in these self-management behaviors (31, 33, 51). Future research could explore potential mediators or moderators to better understand the underlying mechanisms.

The results of the current study should be understood in the context of several limitations. First, this study focused on a specific population of Latinos with T2D living in Southern California, thereby limiting the generalizability of these findings to other Latino populations in different demographic regions or healthcare settings. This study also focused on engagement and adherence within the context of a specific mHealth DSME/S intervention (Dulce Digital-Me). Other mHealth interventions may have unique features or delivery methods that influence these outcomes differently. Second, engagement and adherence in the intervention were operationalized based on completion rates of various intervention components (EMA, coaching call, pillbox, and BG completion). While these outcomes provide insight into participants' interactions with the intervention and are our best way to quantify engagement and adherence, they may not fully capture the quality or depth of these outcomes. Third, the coaching call outcome was limited to those in the DD-Me-Tel group only (about one third of the total sample), which may have impacted power and ability to detect significant associations. Fourth, this study utilized a cross-sectional design, which limits the ability to establish causal relationships between predictor variables and outcomes. Longitudinal research is recommended to better understand the temporal relationships between these variables.

Conclusions

Overall, our study provides valuable insights into the demographic and psychosocial factors influencing engagement and adherence in this understudied population. Notably, these factors primarily influenced participants' engagement with intervention components rather than their adherence to specific diabetes self-management behaviors like checking BG and taking medications, which may be more complex and nuanced in nature. Our study underscores the need for tailored approaches to address identified barriers to engagement, particularly among older adults, those with limited health literacy, and those experiencing higher levels of distress at baseline. By addressing these barriers and leveraging cultural strengths, future mHealth interventions can better support Latinos with T2D and improve health outcomes in this vulnerable population.

Chapters 3, in full, is currently being prepared for submission for publication of the material. Clark TL, Philis-Tsimikas A, Fortmann AL, Roesch SC, Spierling-Bagsic SR, Schultz J, Godino JG, Rutledge T, Afari N, Talavera GA, Horvath KJ, Gallo LC. Do Participant Characteristics and Diabetes Distress Levels Predict Participant Engagement and Adherence in a mHealth DSME/S Intervention? The dissertation author was the primary investigator and author of this paper.

4. Improved Glycemic Management Following a mHealth DSME/S Intervention: What is the Role of Diabetes Distress?

Clark TL, Philis-Tsimikas A, Fortmann AL, Roesch SC, Spierling-Bagsic SR, Schultz J, Godino JG, Rutledge T, Afari N, Talavera GA, Horvath KJ, Gallo LC.

Abstract

Purpose: This study investigated the relationship between diabetes distress and glycemic control in Latino adults with type 2 diabetes (T2D), enrolled in mobile health (mHealth) diabetes self-management education and support (DSME/S) interventions.

Methods: Participants were from the Dulce Digital-Me parent trial, a randomized comparative effectiveness trial testing three mHealth DSME/S interventions: Dulce Digital (DD), a static intervention with no personalized feedback; DD-Me-Auto, an individualized intervention with automated, text message-based feedback; and DD-Me-Tel, an individualized intervention with telephonic feedback. Participants in the current study included those who completed baseline and 6-month assessments of diabetes distress and hemoglobin A1c (A1c), which was approximately 75% of the total Dulce Digital-Me sample (n=232). Multilevel modeling and linear regression analyses were conducted to examine changes in distress and associations with A1c, controlling for age, sex, and intervention group. Group stratified sensitivity analyses were conducted for descriptive and exploratory purposes only.

Results: Participants were 52.1 (±10.2) years old, 69.7% female, with A1c 9.3% (±1.6) at baseline. Diabetes distress significantly decreased over the intervention period ($p < .001$) with comparable reductions observed across intervention groups. Higher baseline distress was linearly associated with higher A1c post-intervention ($p < .05$), particularly in the DD-Me-Auto group, after control for baseline A1c and other covariates.

Conclusions: mHealth interventions in this study showed promise for improving psychosocial well-being and glycemic control in Latino adults with T2D. This study underscores the need for further research to optimize mHealth interventions for diverse populations with T2D and concomitant distress, given the high prevalence rate observed.

Introduction

Type 2 diabetes (T2D) is a growing public health concern in the United States, with particular impact on Hispanic/Latino/Latinx (hereafter, Latino) adults who experience disproportionately higher rates of the disease and its associated complications (68, 87-91). Despite advancements in diabetes management, this population continues to face barriers to accessing quality healthcare (40, 41, 75), which contributes to poorer health outcomes and elevated levels of diabetes distress (28, 68, 90-92).

Mobile health (mHealth) interventions offer a promising means to expand care to medically underserved groups. While numerous studies have explored the effectiveness of mHealth diabetes self-management education and support (DSME/S) interventions among Latino adults (48, 78), the relationship between diabetes distress and intervention effectiveness remains complex and not fully understood. Several studies have reported reductions in distress following DSME/S (37, 38) and an association between reduced distress with improved diabetes management (indicated by lower Hemoglobin A1c (A1c) levels) (30, 53, 55, 56), while other studies have not illustrated this (57, 58). In fact, in a prior mHealth DSME/S study for Latino adults with T2D, we found that participants with higher levels of distress at baseline exhibited *greater* improvements in A1c following the intervention relative to those with less distress (58). Participants receiving the mHealth DSME/S intervention had similar reductions in distress to those who received care as usual, though only the intervention group illustrated significant improvements in A1c (58). One potential explanation for this finding was that an "optimal" level of baseline distress exists for observing clinical improvements, such that distress that is too high hinders motivation and engagement, while distress that is low (or non-existent) does not provide enough incentive to change. A "moderate" level of stress has been associated with more optimal outcomes and performance in other studies of health behavior change and could be potentially applicable to distress and diabetes outcomes (62, 63). However, we were unable to explore this in the pilot study due to a small sample size and truncated range of distress scores, with 70% of scores falling below the cut-off for "high" distress (i.e., <3 out of a possible 6).

Thus, to better understand the relationship between distress and clinical responsiveness, the current study examined changes in diabetes distress (Aim One) and whether baseline distress (both the linear and quadratic effects; Aim Two) or changes in distress (Aim Three) were associated with improvements in A1c in the context of a larger mHealth DSME/S intervention (Dulce Digital-Me). The quadratic effect of distress was tested to assess the presence of a nonlinear, inverted U-shaped relationship between distress and A1c to determine whether moderate levels of distress were more optimal than low or high levels. Consistent with the patterns observed in Clark et al. 2020, we hypothesized that diabetes distress scores would decrease significantly over time. We also hypothesized the quadratic effect of baseline distress would be significantly related to A1c at month-6, such that moderate levels of baseline distress would result in better clinical outcomes. We did not anticipate that change in distress would be significantly associated with change in A1c.

Methods

The research protocol was approved by the Institutional Review Boards of the participating institutions and all participants provided informed consent. The trial protocol for the Dulce Digital-Me randomized trial has been published (95) and the report of the primary outcomes is currently under review. The current study's analytic sample included participants recruited as part of the Dulce Digital-Me trial (parent study) who had valid A1c and diabetes distress data at baseline and month 6 (n=232; 75% of the total sample). Primary reasons for non-completion at month 6 included 1) unable to reach participant for follow-up and 2) reached participant, but unable to schedule a follow-up visit within the appropriate timeframe. The CONSORT diagram is available in the primary outcomes paper (Philis-Tsimikas et al., 2024, under review).

Participants and Setting

The parent study, Dulce Digital-Me, recruited N=310 Latino adults aged 18 years or older who were registered patients at a Federally Qualified Health Center (FQHC) in San Diego, California. Eligibility criteria included a diagnosis of T2D <u>and</u> A1c ≥ 8.0%, and/or SBP ≥ 140, and/or LDL-C ≥ 100 mg/dL. Exclusion criteria were severe illness precluding regular clinic visits; pregnant or lactating; type 1 or gestational diabetes; lack of minimal literacy; severe auditory or visual problems; primary language other than Spanish or English; not willing to carry a mobile phone; and plans to relocate.

Study Design and Procedures

Recruitment and Initial Visit. Automated electronic health record (EHR)-derived reports were used to identify eligible patients in collaboration with the FQHC partner. From October 2017 to February 2020, eligible patients were invited to an initial visit where the study was explained, written consent obtained, and baseline assessments conducted. This assessment included a lab draw to obtain baseline A1c and a patient-reported outcomes survey. Participants were asked to return 6 months later to repeat both the lab draw and surveys. A COVID-19 protocol was developed to conduct follow-up surveys by phone instead of in person and was in effect from March 2020 until the end of the study. All completers were given a small gift card for their participation (95).

Measures. Diabetes distress was assessed using the Diabetes Distress Scale-17 (DDS-17) at both the baseline visit and 6-month follow-up assessment, in either English or Spanish (25, 98). Participants rated their distress levels across four domains (emotional burden, physical-related, regimen, and interpersonal) over the past month using a 6-point Likert scale. Total scores (item averages) were used in analyses and established cut-offs were used for descriptive purposes (<2.0= no or low distress, 2.0-2.9=moderate distress, ≥3.0=high distress). The DDS-17 exhibited strong internal consistency in the current sample ($\alpha = 0.93$). A1c at baseline and month-6 were obtained following an 8-12 hour fast and were processed by Quest Diagnostics Inc. using Immunoturbidimetry (Integra 800 Roche; (95)).

Study Devices. All participants were given a wireless-enabled glucometer, pillbox, and cell phone at the initial visit (unless they preferred to use their personal cell phone). The glucometer transmitted blood glucose data to a secure platform in real time. Participants were asked to use the pillbox for their diabetes medications, which then transmitted medication adherence data to the secure platform each time opened. Participants used cell phones to 1) receive core educational content and 2) respond to ecological momentary assessments (EMAs) of health behaviors and well-being.

Intervention Groups. Participants were randomly assigned to one of three intervention groups using a 1:1:1 equal allocation ratio: Dulce Digital (DD), Dulce Digital-Me Automated (DD-Me-Auto), and Dulce Digital-Me Telephonic (DD-Me-Tel). DD participants received standardized text messages covering various self-care domains without any tailored goal setting or feedback. DD-Me-Auto participants received the DD intervention, plus adaptive goal setting and feedback based on their data from the secure platform, delivered via text message using a computer-driven algorithm. DD-Me-Tel participants received the DD intervention plus adaptive goal setting and feedback delivered via once-weekly calls with a health coach. All three interventions lasted for 6 months, and all participants received routine diabetes care throughout the study (95).

A manuscript reporting analyses examining group-based differences in primary and secondary outcomes is currently under review. In summary, we observed a statistically significant reduction in A1c across groups from baseline to month 6 (meanΔ per month = -0.17, 95% CI [-0.20,-0.14]; p < 0.001), with no significant Group x Time effect ($p > .05$). Group stratified analyses showed similar and statistically significant changes within each intervention group (Philis-Tsimikas et al., 2024, under review).

Statistical Analysis

All analyses were performed using SPSS (IBM Corporation 1989, 2016) and MPlus V8.9. A significance level of $p < .05$ (two-tailed) was used to determine statistical significance. To assess Aim One, multilevel modeling was used with Distress (modeled continuously) as the specified outcome of interest and Time (months between assessments) as the effect of interest, controlling for age, sex, and intervention group. Full-information maximum likelihood (FIML), an approach that uses all available data to estimate parameters and generates unbiased parameter estimates and standard errors, was used to account for missing data. To assess Aim Two, multivariable linear regression was used to examine whether baseline distress predicted A1c at month 6, controlling for age, sex, intervention group, time between A1c assessments, and baseline A1c. To assess the presence of a nonlinear relationship between distress and A1c, we also hierarchically examined a second model that tested the quadratic effect of baseline distress. The two models were compared by examining change in R^2 to determine better fit. All variables were modeled continuously, except sex (male=reference category) and intervention group (DD=reference category). Valid cases for Aim Two analyses were limited to those who completed the month-6 A1c lab draw, which was approximately 73% (n=226) of the total sample. For descriptive purposes, group stratified sensitivity analyses were conducted for Aims One and Two to see if effects differed in magnitude based on intervention received. P-values are included for informational purposes only, and effect magnitude and patterns of associations are emphasized.

To assess Aim Three, we first used multilevel modeling to examine whether there was a statistically significant degree of person-level variability in change in distress over time (baseline to month 6). However, the initial model showed a lack of significant person-level variability, which precluded further exploration of the relationship between change in distress and change in A1c using multilevel modeling.

Results

Descriptive Statistics

Table 7 presents baseline characteristics of all participants. On average, participants were 52.1 years old (±10.2) and predominantly female (n=216; 69.7%). All identified as Latino per study criteria, with 90.6% (n=281) born in Mexico and 93.2% (n=289) preferring Spanish. Most had less than a high school education (n=230, 74.9%), annual household income <=$20,000 (n=189; 66.5%), and were unemployed (n=168; 54.5%). The average duration of diabetes was 10.4 years (±8.2) with a mean A1c of 9.3% (±1.6) at baseline. Across groups, the mean total

DDS-17 score at baseline was 2.4 (±0.9), suggesting a clinically meaningful level of distress. Approximately 60% of the sample had a DDS-17 baseline score in the moderate or high range (DDS-17 $\geq$ 2.0).

Table 7. *Participant Characteristics in Total Sample (N=310)*

Variable	n (%)
Demographic Variables [a]	
Age (years), M (SD)	52.1 (10.2)
Female	216 (69.7%)
Hispanic/Latino ethnicity	310 (100.0%)
Less than high school education/GED	230 (74.9%)
Yearly household income	
<= $20,000	189 (66.5%)
>$20,000-$30,000	49 (17.4%)
>$30,000	46 (16.2%)
Employment	
Not employed	168 (54.4%)
Employed (Either part-time or full-time)	141 (45.6%)
Marital status	
Not married or living with partner	107 (34.5%)
Married/Living with partner	203 (65.5%)
Place of birth	
United States	20 (6.5%)
Mexico	281 (90.6%)
Other	9 (2.9%)
Preferred Language	
English	21 (6.8%)
Spanish	289 (93.2%)

Table 7 Continued.

Variable	n (%)
Insurance	
Uninsured	158 (51.0%)
Insured (Any)	152 (49.0%)
Health Literacy [b]	
Adequate	167 (53.9%)
Limited	143 (46.1%)
Clinical Variables	
Duration of diabetes diagnosis, years, M (SD)	10.4 (8.2)
BMI, kg/m^2, M (SD)	32.3 (6.6)
A1c, % M (SD)	9.3% (1.6)
SBP, mm/Hg, M (SD)	122.5 (18.4)
LDL-C, mg/Dl, M (SD)	94.6 (38.3)
Diabetes distress, M (SD) [c]	2.4 (0.9)

Abbreviations: GED= General Education Development Test; BMI=Body Mass Index.
[a] Sample sizes differ due to missing data for individual variables.
[b] Health literacy was assessed using the Single Item Literacy Scale (SILS; adequate or limited).
[c] Diabetes distress was assessed using the Diabetes Distress Scale-17 (total score). Total scores can range from 1.0 to 6.0, and ≥2.0 has been established as a clinically meaningful cut point for the DDS-17.

Inferential Statistics

Table 8 presents results from Aim One analyses, which revealed that diabetes distress decreased significantly from baseline to month 6, after controlling for age, sex, baseline A1c, and intervention group (B=-.02, 95% CI [-0.03, -0.01], $p < .001$). Unadjusted mean change in DDS-17 total score for the entire sample from baseline to month-6 was -0.23, which approached the previously established minimal clinically important difference for the DDS-17 of -0.25 (112). Group stratified sensitivity analyses revealed that the degree of change was comparable across groups, though reductions in distress were slightly larger in magnitude (and statistically significant) in the DD (B=-.03, 95% CI [-0.05, -.005]) and DD-Me-Tel groups (B=-.03, 95% CI [-0.06, -0.01]) relative to DD-Me-Auto (B=.00, 95% CI [-0.03, 0.02]). Aim Two analyses illustrated a statistically significant linear relationship between baseline distress and month-6 A1c, such that a 1 unit increase in DDS-17 total score at baseline was associated with a 0.20% higher A1c at month-6 (B=.20, 95% CI [.01, .40], $p < .05$), after controlling for age, sex, intervention group, and baseline A1c (Table 8). The quadratic effect of baseline distress was not significant and the addition of it to the model did not improve variance explained or model fit, suggesting a linear, rather than curvilinear relationship (all *p*s > .05). Group stratified sensitivity analyses revealed that the positive, linear association between baseline distress and month-6 A1c was of larger magnitude and statistically significant in the DD-Me-Auto group (B=.45, 95% CI [.07, .82], $p < .05$), relative to the DD (B=.07, 95% CI [-.28, .43], p=.53) and DD-Me-Tel groups (B=.10, 95% CI [-.22, .42], p=.69). As noted, Aim Three analyses were not conducted due to a lack of person-level difference in changes in distress.

Table 8. *Descriptive, Aim One, and Aim Two Results for Total Sample and Group Stratified Sensitivity Analyses*

	Descriptive Results		**Aim One Results**			**Aim Two Results**
Group	**Baseline A1c, M % (SD)**	**Month-6 A1c, M % (SD)**	**Baseline Diabetes Distress, M (SD)**	**Month-6 Diabetes Distress, M (SD)**	**[a] Within Group Slope for Diabetes Distress B (95% CI), p**	**[b] Baseline Distress B (95% CI), p**
Total Sample (N=310)	9.31 (1.59)	8.20 (1.54)	2.39 (0.99)	2.16 (0.91)	-0.02 (-0.03, -0.01) p = 0.001	0.20 (0.01, 0.40) p < .05
DD (n=107)	9.25 (1.64)	8.17 (1.51)	2.37 (1.00)	2.14 (0.83)	-0.03 (-0.05, -.005) p = 0.03	0.07 (-0.28, 0.43) p=.53
DD-Me-Auto (n=106)	9.31 (1.58)	7.99 (1.61)	2.38 (1.00)	2.15 (1.00)	0.00 (-0.03, 0.02) p = 0.67	0.45 (0.07, 0.82) p < .05

DD-Me-Tel (n=97)	9.37 (1.56)	8.44 (1.48)	2.40 (0.97)	2.18 (0.90)	-0.03 (-0.06, -0.01) p = 0.007	=0.10 (-0.22, .42) p=.69

[a] Results from multilevel models examining Distress (modeled continuously) as the specified outcome of interest and Time (months between assessments) as the effect of interest, controlling for age, sex, and intervention group. Intervention group was included as a covariate in the total sample row only.
[b] Results from multivariable linear regression models examining whether baseline distress predicted A1c at month 6, controlling for age, sex, time between A1c assessments, and baseline A1c. Intervention group was included as a covariate in the total sample row only.

Discussion

This study contributes to the growing body of literature examining diabetes distress and its relationship to clinical outcomes, particularly in the context of mHealth interventions. Consistent with previous DSME/S interventions (37, 38), this study found a significant and clinically meaningful reduction in distress over the 6-month intervention period across groups, underscoring the potential of mHealth DSME/S interventions to positively impact both clinical (Philis-Tsimikas et al., 2024; under review) *and* psychosocial outcomes. This is promising considering these interventions can be delivered entirely by cell phone, which is less burdensome, resource-intensive, and more accessible than traditional, in-person DSME/S or other psychosocial interventions. The current study also helped fill a gap identified by a previous systematic review, which noted a lack of large-scale randomized controlled trials reporting changes in distress following DSME/S interventions in Latino adults specifically (38).

While the current study was underpowered to formally test group-based interaction effects, group stratified sensitivity analyses were conducted for descriptive purposes. Reductions in distress across the study intervention period were similar across groups, though slightly smaller in the DD-Me-Auto group. Additionally, the positive, linear relationship between baseline distress and month-6 A1c was of larger magnitude (and statistically significant) in the DD-Me-Auto group. A prior DD-Me process evaluation reported that the DD-Me-Auto group was also less engaged in the study, exhibiting a significantly lower EMA response rate than other groups (111). However, all groups, including DD-Me-Auto, showed significant clinical improvements following the intervention with no statistically significant between-group differences in level of changes in A1c, as reported in the primary outcomes paper (Philis-Tsimikas et al., 2024, under review). While the current results must be interpreted with caution, there are several possible explanations for these findings. Unlike the DD group, both the DD-Me-Auto and DD-Me-Tel groups received additional feedback about their engagement, or lack thereof, in diabetes self-management behaviors based on electronically transmitted BG, EMA, and medication adherence data. The DD-Me-Tel group received this feedback in the context of 1:1 coaching calls with a linguistically and culturally concordant health coach, whereas the DD-Me-Auto group received this feedback in the form of algorithm-generated text messages. For those in the DD-Me-Tel group, this interpersonal contact, which likely included emotional support, validation, and more dynamic, personalized problem-solving, may have helped participants interpret and utilize feedback in a more meaningful way. As noted, this feedback was also delivered by a coach who shared a similar cultural background and had lived experience with diabetes, which may have capitalized favorably on the Latino cultural value of *personalismo*, or the appreciation for genuine interpersonal relationships, including in healthcare (109, 110). Thus, the addition of feedback but lack of human touch and added experience of “technology fatigue” (111) in this strictly technological intervention arm, might partially explain why we observed trends suggesting less favorable psychosocial and study engagement outcomes within DD-Me-Auto. A prior systematic review concluded that technology-based interventions are effective in reducing diabetes distress, but individualized feedback appears to facilitate better outcomes (113). The current study adds to this literature by suggesting that if individualized feedback is provided, the delivery mode of this feedback might make a meaningful difference, particularly in Latino samples, where interpersonal connection is highly valued.

As mentioned, our previous mHealth pilot study, which tested a text-based intervention similar to the DD condition in the current study (i.e., DSME/S content with no tailored goal setting or feedback) versus a no treatment control condition, found that participants with higher levels of distress at baseline exhibited *greater* improvements in A1c following the intervention compared to those with less distress (58). The current study found that higher distress at baseline was associated with higher post-intervention A1c, and this effect was stronger in the DD-Me-Auto group compared to the DD and DD-Me-Tel groups. Additional research is needed to understand this discrepancy, however, there was a truncated range of distress scores in the prior study (70% of scores fell below 3 out of a possible 6) *and* in the current study, where 73% of scores fell below 3, indicating predominantly low or moderate distress levels. A lack of variability in distress scores across the entire distress continuum may partially explain mixed findings. Additionally, we did not assess other sources of psychological distress (e.g., depression, anxiety, general stress) in either study, which may confound the relationship between diabetes distress and A1c, as these conditions have been shown to affect A1c and frequently co-occur with diabetes distress (32, 114). Future research might consider assessing these factors and testing whether integration of more targeted psychosocial content into the mHealth DSME/S curriculum, using approaches that have been shown to be effective like the REDEEM program (115) and Acceptance and Commitment Therapy (65, 104), further maximizes outcomes.

Despite the insights provided by this study, several limitations should be acknowledged. First, because we did not have a "true" control group, we cannot determine whether reductions in distress reflect true change or regression to the mean. Second, insufficient person-level variability in distress change prevented us from being able to examine the relationship between change in distress and A1c. Third, we were underpowered to test group-based interaction effects in the current study. Including a control group and recruiting a larger sample with more variability in distress scores at baseline could help address these limitations in future research. Additionally, mHealth DSME/S interventions vary widely in terms of delivery modes and features used, and at this time, it is unclear whether associations observed in the current study persist in other mHealth interventions. Future research that is powered to examine between group and within group effects could help elucidate these relationships further.

In conclusion, this study adds to the existing literature by shedding light on the relationship between distress and clinical outcomes in the context of a larger scale mHealth intervention for Latinos with T2D. While mHealth DSME/S interventions hold promise for improving both psychosocial well-being and glycemic control in this population, our findings underscore the important roles of personalized feedback and interpersonal connection in potentially shaping intervention effectiveness. This highlights the need for further research to optimize the design and delivery of mHealth interventions for diverse, minority populations like Latino adults.

Chapters 4, in full, is currently being prepared for submission for publication of the material. Clark TL, Philis-Tsimikas A, Fortmann AL, Roesch SC, Spierling-Bagsic SR, Schultz J, Godino JG, Rutledge T, Afari N, Talavera GA, Horvath KJ, Gallo LC. Improved Glycemic Management Following a mHealth DSME/S Intervention: What is the Role of Diabetes Distress? The dissertation author was the primary investigator and author of this paper.

5. Discussion

Summary

Latino adults in the United States are disproportionately burdened by T2D and experience more complications and greater rates of diabetes distress compared to non-Hispanic White adults (87-89). While DSME/S is effective at improving clinical and psychosocial outcomes, there are a number of practical and healthcare access barriers that complicate DSME/S utilization, particularly among low-income, minority adults (40, 41, 75). mHealth can help bridge care to patients who need DSME/S services, but there is little research exploring how participant characteristics and diabetes distress influence engagement, adherence, and clinical responsiveness to mHealth DSME/S interventions. The current research advanced the literature by clarifying these relationships in the context of mHealth DSME/S interventions designed for Latino adults with T2D, through a series of three studies.

mHealth Engagement and Adherence

Engagement and adherence are crucial to the success of mHealth interventions, yet these metrics have often been underreported in prior diabetes mHealth research studies (49). There is a paucity of research exploring participant characteristics and diabetes distress as predictors of engagement and adherence in mHealth, especially among demographic groups facing barriers to traditional care, such as adults from racial/ethnic minority groups with low-income. Via Study Two, this dissertation contributes to the literature by describing engagement and adherence in a sample of Latino adults with T2D enrolled in mHealth interventions and exploring associations between participant characteristics and diabetes distress with engagement and adherence. Despite insights gained, several gaps and questions remain.

Overall, we observed that completion rates of expected pillbox openings and coaching calls were high (81.3% and 77.1%, respectively), whereas only about half of expected EMA items and BG readings were completed (52.1% and 49.3%, respectively). Participant characteristics and diabetes distress were related to engagement with study-specific mHealth components, such as EMA completion rate and coaching call completion rate, but not self-management focused components like BG checking rate and WP opening rate. Specifically, older age and longer diabetes duration, which were moderately correlated with each other, were both associated with lower EMA completion. Understanding the underlying reasons for these association requires further investigation, particularly regarding potential impact of visual, hearing, and/or mobility limitations among older adults as described in other mHealth studies (100, 101). Health literacy remained a significant predictor of EMA completion despite efforts to develop intervention content suitable for individuals with low literacy and education levels. At this time, it is unclear whether limited health literacy served as a barrier to participants understanding EMAs, responding to EMAs, or both. While EMA items were specific to the Dulce Digital-Me study design, completion of them informed the "individualized" aspect of the intervention, and would have made for a more tailored, rich program if completed at a higher rate. Qualitative research could provide valuable insights into the specific challenges faced by individuals of older age and with lower health literacy in completing EMA items, which could be used to inform adaptation of these interventions for future use.

Moreover, while higher levels of diabetes distress significantly predicted lower EMA completion, distress was not related to other engagement and adherence outcomes, though prior research has often linked it to less engagement in self-management tasks (e.g., checking BG, taking medication) (31, 33, 51). Similar to other emotional states, it is possible that diabetes distress may fluctuate significantly throughout time. The current study assessed diabetes distress at two discreet timepoints (baseline and post-intervention), however, more frequent assessment of diabetes distress, perhaps using an abbreviated tool like the Diabetes Distress Scale-2 delivered via EMA, could allow us to see how distress in "real time" relates to engagement in various behaviors (both study-specific and more general diabetes self-management behaviors). Additionally, participants in Dulce Digital-Me had T2D for an average of ten years at the time of study enrollment and were likely familiar with tasks of diabetes self-management and related tools (e.g., glucometers and pillboxes), but not reading and responding to EMA items. It is also possible that participants in this sample may have been experiencing diabetes distress for an extended period of time already and had found ways to adapt to it in the context of self-management tasks, given the long average duration of T2D diagnosis. These factors may partially explain why distress was a barrier to completing EMA items, but not tasks of self-management. Future research might explore how the relationship between distress and adherence differs among those who are newly diagnosed versus those who have been diagnosed with T2D longer.

Lastly, we observed that preference for Spanish over English language was related to completion of significantly more coaching calls. While speculative, it is possible that linguistic concordance between Spanish speaking participants and the coach may have been helpful in creating a deeper interpersonal, cultural connection (i.e., *personalismo*), resulting in completion of more calls (109, 110). Additional research is needed to see if this finding persists in other studies, and how we might incorporate more cultural components to maximize engagement and adherence in technology-based interventions.

As noted, neither participant characteristics nor diabetes distress predicted completion of BG readings or pillbox openings. While the average pillbox opening rate was high, only about half of BG readings were completed as expected. Although Dulce Digital-Me DSME/S content emphasized the importance of checking BG throughout the intervention, and sent reminders to do so, there are many reported barriers inherent to checking BG including fear of needles, pain, frustration about high blood glucose readings, and inconvenience (116). These factors were not assessed as part of the current study but may explain why BG completion rate was particularly low. Future research might consider integrating more content into the intervention that addresses these barriers or incorporating technology like continuous glucose monitors to circumvent the deterrents inherent to using a standard glucometer.

Clinical Responsiveness

Both Studies One and Three examined the role of diabetes distress in the context of clinical responsiveness (i.e., A1c change) to mHealth DSME/S interventions for Latinos with T2D. As described, Study One reported a significant reduction in A1c in the Dulce Digital group relative to Usual Care, and baseline diabetes distress moderated this effect, such that higher distress at baseline was associated with greater clinical responsiveness (i.e., lower A1c) over time (58). In Study Three, we saw a significant reduction in A1c across all three groups (Dulce Digital (DD), Dulce Digital Automatic (DD-Me-Auto), Dulce Digital Telephonic (DD-Me-Tel)), with no significant between group differences. Higher distress at baseline was associated with *higher* post-intervention A1c (rather than lower A1c) in this study, and when we examined this further by group for exploratory purposes, this effect was stronger (and significant) in the DD-Me-Auto group compared to the DD and DD-Me-Tel groups. Overall, this contradicted findings in Study One suggesting that higher distress was associated with more optimal clinical outcomes.

Regarding reductions in distress over the intervention period, in Study One, we saw comparable reductions in distress for both the Dulce Digital and Usual Care groups, with no significant between group differences. In Study Three, we saw significant, comparable reductions in distress across groups (DD, DD-Me-Auto, DD-Me-Tel), though there was a slightly smaller reduction observed in the DD-Me-Auto group.

Taken together, Studies One and Three results suggest that baseline diabetes distress and changes in distress play a role in shaping clinical effectiveness, but the direction of these effects remains unclear in this population. Evidence across other mHealth and non-mHealth DSME/S interventions predominantly suggests that these interventions reduce distress, and that these reductions are related to reductions in A1c (30, 37, 38, 53, 55, 56). Several limitations in Studies One and Three prevented further exploration of the role of distress in clinical effectiveness and could explain some of the mixed findings observed. First, while the prevalence rate of clinically meaningful distress (e.g., DDS-17 $\geq$ 2.0) was high in both samples, most of these scores fell in the moderate range, which limited our ability to understand how distress across the entire continuum (and particularly on the higher end) was related to A1c. Second, we also observed a lack of within person variability of changes in distress pre- and post-intervention (Study Three), which was surprising, and precluded examination of changes in distress as they relate to changes in A1c. Third, we did not assess for other psychological conditions, such as depression, anxiety, and general stress, in either study, which can co-occur with diabetes distress and affect A1c (32, 114). Assessment of these confounding factors could potentially help us better understand the unique contribution of diabetes distress to A1c change, and examination of each distress subscale, in addition to total score, could further flesh out the role of distress.

Finally, due to lack of statistical power, we were unable to formally examine group-based differences in change in distress over time (i.e., Distress x Group x Time interaction effect) in Study Three. However, exploratory within-group analyses suggested that the specific nature of the intervention received may play an important role in shaping how distress affects A1c. Specifically, those in the DD-Me-Auto group exhibited a slightly smaller reduction in distress over time and a positive, linear relationship between baseline distress and month-6 A1c of significantly larger magnitude compared to DD and DD-Me-Tel. A prior systematic review suggested that individualized feedback in mHealth interventions is associated with better outcomes (113), and results from the current study expand on this further by suggesting that the delivery mode of this feedback (automated vs. live) may be important, particularly in this ethnic-cultural group.

Summary of Clinical Implications and Future Directions

Several clinical implications and directions for future research in the area of mHealth interventions for Latino adults with T2D are summarized. First, while mHealth is a promising avenue to extend the reach of care to medically underserved Latino adults, Study Two of this dissertation, in combination with previous research (100, 102, 103), suggests a need for individualized approaches that consider factors such as older age, lower health literacy levels, and higher baseline distress levels to maximize study engagement. In line with prior recommendations, future research might consider incorporating platforms suitable to varying physical abilities (e.g., vision/hearing/mobility), more extensive technology training, leveraging of support networks to encourage mHealth utilization, and use of plain language and visual aids. Although differences in age, health literacy, and distress related to lower EMA completion rates, more research is needed to understand why BG completion rates were also low and if this persists in other samples. As noted, prior qualitative research has identified several patient barriers to using traditional glucometers (e.g., fear of needles, pain, inconvenience; (116)), and it may be worthwhile to examine whether incorporation of continuous glucose monitors into mHealth DSME/S interventions helps to address some of these barriers and further improve clinical and psychosocial outcomes.

The American Diabetes Association's first line recommendation for adults with diabetes distress is engagement in DSME/S, however, as noted, accessing these services is challenging and utilization is often low (34). Results of this dissertation demonstrated the potential of all three Dulce Digital-Me RCT interventions to positively impact diabetes distress, in addition to clinical outcomes (as discussed in the primary outcomes paper; Philis-Tsimikas et al., 2024, under review). Considering that the prevalence rate of diabetes distress was higher in this sample of Latino adults than what has been reported in a prior meta-analysis of patients with T2D of varying racial and ethnic backgrounds (58% in the current study vs. 36% in the meta-analysis; (27)), this is an encouraging finding. However, it is important to understand what might be contributing to the relatively high rate of distress among Latino individuals. As discussed, more frequent distress assessment and additional assessment of other psychological symptoms (depression, anxiety, general stress) could be helpful in further understanding the unique contribution of diabetes distress. Given that this population may experience additional stressors (e.g., financial, racial discrimination) that could also affect A1c (110), it is important to examine whether supplemental, evidence-based psychosocial support (e.g., Acceptance and Commitment Therapy, Problem Solving Therapy) should be integrated into mHealth DSME/S approaches like Dulce Digital-Me to further enhance clinical, psychosocial, and engagement outcomes (65, 104, 105).

Finally, prior research has shown that individualized feedback in mHealth DSME/S interventions leads to better outcomes (113); however, the current study suggests that the delivery mode of this feedback might make an important difference as well. Across several analyses, we observed that the DD-Me-Auto group was less engaged (111), had a smaller reduction in distress over the intervention course, and exhibited a more persistent effect of baseline distress on A1c following intervention completion. This strictly technological approach may have led to "technology fatigue," resulting in less optimal psychosocial and engagement outcomes. From a clinical perspective, this dissertation highlights the value of the "human touch" when providing individualized feedback, particularly in cultural groups that value genuine, interpersonal relationships. Future research should explore how to best appeal to cultural values like "personalismo" within mHealth interventions to increase cultural sensitivity and maximize outcomes.

Conclusions

In conclusion, this dissertation highlights the value of mHealth interventions for Latino adults with T2D, as they show potential to improve both clinical and psychosocial outcomes. Using data from the Dulce Digital Me RCT (Study Two), current research identified the influences of certain demographic characteristics and baseline diabetes distress on engagement in study-specific mHealth components such EMA completion and coaching call completion, but not diabetes self-management tasks such as BG and pillbox opening completion. In the Dulce Digital pilot study (Study One), reductions in distress were observed for both the Dulce Digital and Usual Care groups, and those with greater distress (DDS-17 $\geq$ 2.0) exhibited more clinical benefit following the intervention than those with low or no distress. In the Dulce Digital-Me RCT (Study Three), reductions in distress were observed in all three Dulce Digital-Me groups and greater distress at baseline was associated with higher A1c at month-6. Several directions for future research are described, including identifying barriers to technology use and adapting mHealth interventions accordingly, integrating psychosocial support, and incorporating culturally sensitive and humanized elements into mHealth approaches for Latino adults with T2D.

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