

**Diabetes Distress Assessment as an Intervention**

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### **Abstract**

Diabetes Distress (DD) is a major concern in the diabetes community due to the negative associated outcomes. This study aimed to determine the effectiveness of consistent DD screening (PAID scale and supplemental questions), as an intervention to reduce DD in diabetic patients. This study uses a single blind experimental design at a Midwest U.S. Endocrine clinic. The sample size for study will be 100, with roughly 50 samples for each group. Individuals that will be included are: 18 years or older, diagnosed with T2DM, and able to speak and read English. Data collection will occur at already scheduled provider appointments and potential subjects will be identified by clinic staff, evaluated for eligibility, and scheduled for follow up clinic visits. Study staff will make random allocation cards using computer generated random numbers. Subjects assigned to the intervention group will have HbA1c obtained, will self-administer the PAID scale, and clinic staff ask three additional questions. The control group will have HbA1c obtained and will self-administer the PAID scale. No additional questions will be asked by the clinic staff for the control group. Unfortunately, this intervention study was put on hold for 2020 due to the COVID-19 pandemic which resulted in a moratorium on research. Because the study was unable to be conducted at this time, the use of the DD Assessment as a patient-tailored intervention, requires further research in order to determine its clinical effectiveness in reducing DD.

*Keywords:* diabetes distress, interventions, assessment, PAID scale

### **Diabetes Distress Assessment as an Intervention**

Distress is a common experience in the diabetic community, yet it is not widely assessed and addressed by medical professionals (Fisher et al., 2019; Martin et al., 2018; Owens-Gary et al., 2019; Yared et al., 2020). Diabetes distress (DD) encompasses intense emotional feelings regarding worries over dealing with the chronic disease. Distress may come from management, possible complications or debilitation, or other concerns (Fisher et al., 2019). Yet while DD encompasses the burden of living with diabetes, it is expected with Type 1 (T1D) and Type 2 diabetes (T2DM) (Kalra et al., 2018) and is not considered its own pathological condition (Fisher et al., 2019). DD is attributed to reduced self-care (Kalra et al., 2018; Kane et al., 2018; Skinner et al., 2020; Yared et al., 2020), weakened emotional well-being, and metabolic issues (Kalra et al., 2018). Some of the emotions attributed to distress are depressive symptoms, dysphoria, worry, psychological symptoms, negative moods, thoughts, and behaviors (Chew et al., 2017).

Approximately 40% of T2DM individuals report DD (Hernandez et al., 2019; Perrin et al., 2017; Yared et al., 2020). Studies have shown that there may be higher risk of DD for elderly individuals and those with comorbidities (Hernandez et al., 2019; Perrin et al., 2017). Additional studies have suggested greater distress associated with females, non-white minority ethnicities, acute diabetic experiences, and lack of support (Barry et al., 2015; Skinner et al., 2020). These risk factors increase the potential of DD and associated symptoms such as increases in HbA1c levels.

The assessment of people who are affected by DD shows an increasing need for interventions to help alleviate the symptoms. In order to offer appropriate interventions for each person individually, assessment by a medical professional is critical. The more tailored the assessments and interventions are, the more likely medical professionals are to decrease distress

and have better outcomes. Current diabetes standards suggest frequent screening for distress, especially in prevention efforts and special populations (American Diabetes Distress [ADA], 2017).

### **Literature Review**

DD is most commonly assessed with the Problem Areas in Diabetes (PAID) and the Diabetes Distress Scale (DDS) instruments. The PAID scale is effective in assessing both T1D and T2DM, whereas the DDS is more in depth and effective for T2DM specifically (Perrin et al., 2017). These scales may help patients identify diabetes-related problem areas and offer interventions to focus on and reach better outcomes.

The PAID scale is the instrument to be used in this study and will be elaborated on further in the following pages. Although the DDS is not the screening instrument for this paper, it is important to mention due to the wide usage of the instrument in identifying DD. The DDS was developed by Polonsky et al (2005) to build on strengths of previous instruments and address their limitations. It captures four critical elements of distress: emotional burden, regimen, interpersonal, and physician distress (Behavioral Diabetes Institute, n.d.; Diabetes Distress Assessment and Resource Center [DDARC], 2017). The DDS is a self-administered 17 item survey. The instrument employs a six-point Likert scale, with 1— “not a problem” to 6— “a very significant problem.” Generally, an average score of less than 2 indicates little or no distress, 2-2.9 indicates moderate distress, and greater than 3 indicates high distress. A total score of greater than 2 is considered clinically significant and warrants further follow-up (DDARC, 2017). This scale allows for precision in assessment and finding particular problem areas to focus on in interventions.

Review of the literature has revealed that DD increases poor outcomes such as risk for mortality, poorly managing the disease, diabetes complications, poor quality of life (Owens-Gary et al., 2019; Martin et al., 2018; Yared et al., 2020), reduced self-care (Kalra et al., 2018; Kane et al., 2018; Skinner et al., 2020; Yared et al., 2020), reduced emotional well-being, and metabolic issues (Kalra et al., 2018). Because of these poor outcomes, T1D and T2DM individuals suffering from DD are in need of innovative interventions that will work to reduce DD in its entirety.

There are currently interventions to reduce some of these negative outcomes associated with DD (such as HbA1c), however, the effectiveness of interventions treating all aspects to DD (both mental and physical health) is nearly non-existent. Some studies have shown that T1D and T2DM individuals who reported greater levels of burden and self-criticism from the physical symptoms of DD, showed higher levels of DD at follow-up. With these patients, the researchers noted that the physical symptoms played a role in increasing the use of negative cognitive emotion regulation. Because of this, these researchers believe that greater amounts of burden from physical symptoms of DD may influence mental health aspects such as poor coping strategies (Kane et al., 2018). The complex relationship between the physical and mental health issues associated with DD, show just how cyclical the nature of this diagnosis can be. An imbalance in either the physical or mental health in these patients with diabetes, can influence the other health outcomes. The physical and mental health of individuals are different aspects to health, and therefore, increasing one of these outcomes does not guarantee an increase in the other. Many different DD interventions that are commonly used today target either physical or mental health outcomes even though current research suggests that for best outcomes, interventions should target both simultaneously. Therefore, the individuals in the diabetes

community are in need of an intervention focusing on their entire health, both physical and mental.

Expanding on this idea, according to Harkness and co-writers (2010), their analysis in their meta-regression showed that very few interventions for DD have a substantial positive impact on both the physical and mental health outcomes. A systematic review and meta-analysis of 41 randomized controlled trials by Sturt et al (2015), showed that effective interventions for DD included psychoeducation, general health interventions, greater than six interventional sessions, greater than three-month intervention duration, and motivational interviewing. Each of these interventions had the strongest effects when engaging emotions in addition to either behavior change or education (Sturt et al., 2015). While these interventions had some success, the interventions fell short in addressing both the physical and mental health aspects.

As suggested above, psychological, educational, behavioral, and emotional approaches are the most common DD interventions because they are seen as somewhat effective (Barry-Menkhaus et al., 2020). These four main DD interventions fall under two main study approaches. The diabetes management approach accounts for education, management of medications, and initiating behavior change to improve glycemic control and the emotional approach suggests addressing the underlying feelings, expectations, and beliefs regarding DD (Fisher et al., 2018).

### **Psychological Interventions**

Psychological interventions are among the most common DD interventions. Most psychological interventions include multiple treatment packages, consisting of many sessions over an extended period of time (Barry-Menkhaus et al., 2020). They are common due to a small positive impact on confidence in self-care (Chew et al., 2017) and HbA1c (Chew et al., 2017; Schmidt et al., 2018). These positive impacts are of low-quality evidence, however, meaning

that the authors are uncertain of how these interventions impact the outcomes above (Chew et al., 2017). Additionally, there is little known about the efficacy of the psychological interventions in treating DD (Kane et al., 2018; Schmidt et al., 2018). It should be noted, however, that there is likely no adverse events due to these interventions when compared to usual care (Chew et al., 2017).

In addition, one systematic review indicated that compared to usual diabetes care, psychological interventions have “no firm effect” on relieving DD, quality of life, death, blood pressure, or adverse events (Chew et al., 2017). Harkness and co-writers (2010) performed a meta-regression study which was included in Chew’s systematic review. They found that of all of the effects that psychological interventions impacted, the greatest benefits were mental health related (Chew et al., 2017; Harkness et al., 2010). The main positive mental health effects included increasing emotional well-being, quality of life, and reducing depression symptoms (Chew et al., 2017). While psychological interventions seem to have somewhat of a positive impact on patients’ mental health, the psychological interventions fall short in addressing DD associated issues entirely.

### **Educational Interventions**

Educational interventions are also commonly used to combat DD, specifically because they have greater effects on HbA1c levels (Chew et al, 2017; Harkness et al, 2010). These interventions have had some success in reducing HbA1c levels and improving glycemic control in T1D, which is essential for improving diabetes outcomes. Educational interventions are often paired with behavioral interventions because of the greater effectiveness of lowering the HbA1c when the two types of interventions are used together (Barry-Menkhaus et al., 2020). The gold standard currently for educational interventions is face-to-face group sessions regarding self-

management. However, the attendance to these sessions is low (Celik et al., 2020). Low attendance is likely due to the larger commitment than other such remote educational programs in addition to the ability of the setting to operationalize the type of visit and see it come to fruition.

The Diabetes Self-Management Education Program (DSME) is commonly used as an educational intervention and its objective is to improve health status (Emery et al., 2019). The DSME is a health intervention that is evidence-based and guided by ADA standards. It is commonly used as an educational tool in DD because it helps people with T1D and T2DM develop the necessary knowledge, abilities, and skills, which empowers them to manage DD more effectively (Barry-Menkhaus et al., 2020; Emery et al., 2019). For instance, a systematic review of reviews by Greenwood et al (2017) wrote that 18 of the 25 systematic reviews discovered technology based DSME had been effective in improving HbA1c in diabetes populations. Because of the relative effectiveness of improving some aspects to the diabetes patient's health such as self-care (physical health), the DSME is widely encouraged for all people with diabetes (Celik et al., 2020).

Another self-management education intervention includes digital consulting. This may include a diabetic patient inputting their knowledge, emotional responses, blood glucose levels, or receiving professional feedback. Celik and co-writers (2020) found in their systematic review that online educational interventions had statistically significant improvements in HbA1c ( $P < 0.0001$ ). Additionally, the results from a study by Fisher and co-writers (2018), showed that educational interventions led to dramatic reductions in DD, again pertaining to the HbA1c exclusively. This study's significant reductions in HbA1c occurred between the start of the study and three months later (Fisher et al., 2018). The statistically significant results from the



educational interventions are reassuring, however, when we look at the patient collectively, both mentally and physically, again these interventions fall short.

### **Behavioral Interventions**

There are many different behavioral interventions, and their efficacy is currently unknown (Chew et al., 2017). Behavioral interventions are typically put into four categories of factors to change: motivators, inhibitors/facilitators, intentions, and triggers. Motivators encourage a specific behavior, inhibitors/facilitators reduce the likelihood of a behavior (considered barriers), intentions are the proximity to behavior change, and triggers are events that shift a person into an action state. The behavioral interventions are also based on the patient-centered approach where the patient must implement their own diabetes self-care and have an internal motivation to change. Healthcare providers help initiate these interventions by fostering patient autonomy through supporting the patient's efforts in change and tailoring the interventions to each specific patient (Peyrot & Rubin, 2007).

Behavioral interventions include behavioral education, setting goals, improving problem solving skills, cognitive behavioral therapy (Barry-Menkhaus et al., 2020; Chew et al., 2017; Peyrot & Rubin, 2007), communication skill building, family conflict resolution, coping skills training, and stress management training (Barry-Menkhaus et al., 2020; Peyrot & Rubin, 2007). Trials of these interventions in the Chew systematic review did not show consistent positive effects related to well-being, self-management skills, or disease control. Other trials have suggested that these interventions are most effective in people with a lower baseline psychological state or lower glycemic control (Chew et al., 2017).

In order to get more consistent results, many studies, as cited before, combine both behavioral interventions and educational interventions (Barry-Menkhaus et al., 2020). This is an

attempt to promote change behaviors in such a way to increase health of the individual with T1D or T2DM. With inconsistent results and low-quality evidence regarding the effectiveness of behavioral interventions, it is important that the research for more holistic treatment for DD continues.

### **Emotional Interventions**

Emotional interventions can also be effective to a certain degree. The systematic review by Chew and co-writers suggest that emotions may play an important role in self-care practices and outcomes. The systematic review recognizes the probable conclusion that positive feelings and resiliency may help prevent negative diabetes related outcomes such as distress and depression, leading to better self-management, greater adherence to exercise and healthy eating, lower HbA1c, and fewer diabetic complications (2017). Emery and co-writers (2019) also suggest that emotional well-being is essential in managing DD and that emotional dysfunction can affect how the diabetes is managed, the ability to maintain metabolic control, and diabetes health outcomes (Emery et al., 2019).

Between the main DD interventions (psychological, educational, behavioral, and emotional interventions), different aspects of health can be managed, but one intervention rarely covers all aspects to an individual's health. Many times, because of this, a few different types of interventions are used together such as educational and behavioral, as cited before. The diabetes community is in need of an intervention that will offer consistent results in managing both the mental health and physical health aspects. Because of the inconsistencies in these areas, there is a need to expand research in the effectiveness of these interventions and expand the creation of new interventions to combat DD in its entirety.

### **Proposal of Action**

The American Diabetes Association recommends early and consistent screening for individuals at risk for DD (Owens-Gary et al., 2019), yet this is not common practice (Fisher et al., 2019; Martin et al., 2018; Owens-Gary et al., 2019; Yared et al., 2020). A Canadian study found that while there is intention of health-care providers to address psychological problems associated with diabetes, the actual practice of addressing these problems is uncommon. This study suggests that one reason for low usage of screening tools (DDS) is attributed to endocrinologists and diabetes educators not realizing the potential benefits of the screening. Because of the low rate of addressing individuals suffering from DD, Canada's diabetes clinical practice guidelines recommend regular screening and the use of self-report questionnaires to assess DD. These questionnaires allow for clinicians to objectively quantify DD issues and track the changes over time (Yared et al., 2020).

A few clinics and studies have tried to combat the low screening by routinely assessing patients in the waiting room or online. The results were then scored and discussed with their health care provider. This increased compliance and empowered patients to make changes in their lifestyle. Recommendations from these previous clinical studies include having available tools to assess DD, making the DD assessment a standard of care and a part of normal examinations, having diabetes specialists address diabetes-related concerns, and having health care providers that are trained to assess and respond to different emotions related to DD (Yared et al., 2020). The purpose of this paper is to expand on these studies by evaluating the effectiveness of consistently screening for DD through administering diabetes distress scales (PAID) along with supplemental questions, as an intervention to reduce physical and mental health DD burdens in diabetic patients in the clinical setting.

## **Materials and Methods**

### **Design, sample, setting**

This study uses a single blind experimental design with random allocation into groups. The sample size for study will be 100, with roughly 50 samples for each group. The use of frequent screening and supplemental questions as an intervention to decrease DD will be implemented at an Endocrine clinic in the Midwest U.S. with approximately 2500 individuals with T2DM. Individuals that will be included are: 18 years or older, diagnosed with T2DM, and able to speak and read English.

### **Data collection**

The study will be approved by the Institutional Review Boards (IRB) at the researchers' university and clinic institution. Data collection will occur at already scheduled provider appointments avoiding additional visits for patients. Potential subjects will be identified by clinic staff, evaluated for eligibility, and scheduled for follow up clinic visits. Study staff will make random allocation cards using computer generated random numbers. Upon arrival to the clinic for the provider appointment, clinic staff will re-explain the study to eligible individuals and obtain informed consent. Clinic staff members will obtain the already prepared random allocation card for the subject upon arrival at this visit.

Subjects assigned to the intervention group will have HbA1c obtained, will self-administer the PAID scale, and clinic staff ask three additional questions. The control group will have HbA1c obtained and will self-administer the PAID scale. No additional questions will be asked by the clinic staff for the control group. HbA1c will be collected during the office visit for all subjects, using the clinic quality-controlled equipment. Data collection will take

approximately five minutes. Subjects allocated to the intervention group will have a 2-week follow up phone call by clinic staff. Subject will complete the PAID questionnaire via phone with the clinic nurse and results will be documented. Time 1 and time 2 data collection will be compared to identify any effectiveness in reducing DD. All data collection will occur within the clinic patient room for confidentiality.

### **Variables, measures**

The demographic variables will be collected with a demographic questionnaire. Variables include gender, age, ethnicity, education, employment status, medical insurance, and household income. These are important data elements to collect in order to summarize the study sample. There are other demographic variables that are important to mention due to the impact on diabetic outcomes. First, length of diabetes since diagnosis will be captured in years. This data element may be impactful as there may be differences in DD based on the years since diagnosis. As one can imagine, the initial diagnosis can create tremendous feelings which may change over time as one copes with living with a chronic illness. Second, treatment regimen will be self-reported. Subjects will indicate treatment category of oral, combination, insulin injection, or lifestyle treatment. It is known that treatment regimen is one source of distress and is important to consider as a variable to explain outcomes (Polonsky et al., 1995). It would be expected that more intense or invasive treatment interventions would indicate higher HbA1c results and higher distress. Conversely, it would be expected that lifestyle and oral treatment regimens would have lower HbA1c and distress, resulting from fewer invasive strategies that would be needed to control blood glucose and prevent complication. Lastly, collaboration with the provider and health care team may indicate better management and in turn, less distress. Therefore, these data elements will be collected during the study.

T2DM distress will be measured using the Problem Areas in Diabetes (PAID) scale. The PAID scale (Polonsky et al., 2015) is the most commonly used and widely accepted instrument for assessing DD and captures the breadth and severity of emotional distress from living with T2DM, including guilt, anger, frustration, depressed mood, worry and fear. It is a valid and reliable tool and is effective at finding changes over time after various interventions. The PAID scale is self-administered with 20 items that captures common negative emotions associated with diabetes. The instrument takes approximately five minutes and employs a five-point Likert scale response with a possible answer of 0—being “no problem” to 4—being “severe problem.” Scores are added and multiplied by 1.25, generating a total score between 0 and 100, with higher scores indicating greater distress. Scores greater than 40 are considered clinically significant and require attention of medical professionals (Polonsky et al., 1995; Martin et al., 2018; Snoek & Welch, 2006). In addition to the PAID scale, this study adds a few supplemental questions which are still under review with clinic nursing and provider leadership.

In addition to the scale and supplemental questions, data will also be collected on glycemic control, measured by HbA1c. This test measures the amount of glucose that attaches to the body’s hemoglobin. Based on current guidelines, a reasonable HbA1c result for an individual with diabetes is <7% (U.S. National Library of Medicine, 2020). HbA1c will be performed via fingerstick and analyzed by clinic staff.

### **Analysis**

The study sample will be characterized using demographic and clinical variables. Mean and standard deviation will be reported for continuous variables and frequencies and percentages will be reported for categorical variables. Pearson’s correlation coefficient or Spearman’s rank correlation coefficient will be used to test for associations based on the sample distribution.

Additional testing will be completed to evaluate for multicollinearity via the variance inflation factor if needed. The two groups will be compared with t-tests or the Mann-Whitney test. In addition, Cronbach's alpha will be run on the instrument in the study.

Data will be analyzed with SPSS 26 statistical software with support of a South Dakota State University statistician. The level of significance will be set at  $\alpha=0.05$ . Data will be cleaned by way of detection and removal of errors. Mean imputation will be used if missing data is present in any of the PAID instrument items with the general guideline of less than 10% of missing values being acceptable.

### **Results**

This intervention study was put on hold for 2020 due to the COVID-19 pandemic which resulted in a moratorium on research in the Midwest clinic as well as the inability of visitors to enter the organization. Ongoing planning for the start of this study will occur Spring 2021. Collaboration with the specialty clinic education nurses, nursing, and provider leaders has been underway. This study is pending organizational nursing research council and IRB approval. The study team does not anticipate barriers to approvals once the moratorium has been lifted.

### **Conclusion**

As many as 40% of T2DM patients report DD (Hernandez et al., 2019; Perrin et al., 2017; Yared et al., 2020), showing that DD is common among diabetes patients. DD includes intense worry over the chronic disease and may result from management, possible complications, or other concerns with the disease (Fisher et al., 2019). Even though part of this disease is an emotional burden, it is expected in T1D and T2DM (Kalra et al., 2018). This emotional burden commonly leads to reduced self-care (Kalra et al., 2018; Kane et al., 2018; Skinner et al., 2020; Yared et al., 2020), weakened emotional well-being, and metabolic issues (Kalra et al., 2018).

The emotions commonly attributed to distress are depressive symptoms, dysphoria, worry, psychological symptoms, negative moods, thoughts, and behaviors (Chew et al., 2017). These symptoms of DD are shown to be higher in elderly individuals, individuals with comorbidities (Hernandez et al., 2019; Perrin et al., 2017), females, non-white minority ethnicities, people with acute diabetic experiences, and people with lack of support (Barry et al., 2015; Skinner et al., 2020). These risk factors increase the potential of DD and associated symptoms such as increases in HbA1c levels.

The current diabetes standards suggest frequent screening for distress, especially in prevention efforts and special populations (American Diabetes Distress [ADA], 2017). DD, however, is still not routinely assessed and addressed in healthcare (Fisher et al., 2019; Martin et al., 2018; Owens-Gary et al., 2019; Yared et al., 2020). While there is intention of health-care providers to address psychological problems associated with diabetes, the actual practice of addressing these problems is uncommon in part due to diabetes educators not realizing the potential benefits of the screening or due to challenges with operationalizing the screening process in practice. Recommendations to improve screening and interventions for DD include having available tools, making the DD assessment a part of normal examinations, having diabetes specialists address diabetes-related concerns, and having health care providers that are trained to assess and respond to different emotions related to DD (Yared et al., 2020).

The large number of people who are affected by DD and the lack of routine assessment and addressment of DD in the medical field contributes to reduced effectiveness of interventions in clinical practice. In addition to lack of assessment, most current DD interventions are targeted at either physical or mental health improvement in these individuals, also leading to ineffective interventions. An imbalance in either the physical or mental health in these patients with



diabetes, can influence their health outcomes which is why current research suggests that interventions should target both physical and mental health simultaneously. Since most current interventions are not equipped to address both of these outcomes, the individuals in the DD community are in need of new interventions that focus on their entire health, both the physical and mental side.

The current leading DD interventions (psychological, educational, behavioral, and emotional approaches) are the most common because they are seen as somewhat effective (Barry-Menkhaus et al., 2020). The psychological and emotional interventions are most effective in improving mental health DD symptoms, whereas educational and behavioral interventions are most effective in improving physical health DD symptoms such as HbA1c levels. Because of the limited number of effective interventions reducing DD overall (physical and mental health symptoms), there is a need for more tailored, patient-centered approaches along with increased screening. The need for an intervention that may address both of these aspects to health was the intention behind this study. Henceforth, the objective of the study was to determine the effectiveness of consistent DD screening by administering the PAID scale along with supplemental questions, as an intervention to reduce physical and mental DD in diabetic patients in the clinical setting.

Due to the COVID-19 pandemic, this intervention study was delayed until 2021. The collaboration and preparations in this study lay the groundwork for potential advances in DD reduction through routine screening and assessment as an intervention. The use of the DD assessment as a patient-tailored intervention, requires further research in order to determine its clinical effectiveness in reducing each aspect to DD.

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