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Perceived Financial Burden, Self-Management Behaviors, and Glycemic Control in Adults with Type 1 Diabetes

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

by

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Abstract

PERCEIVED FINANCIAL BURDEN, SELF-MANAGEMENT BEHAVIORS, AND GLYCEMIC CONTROL IN ADULTS WITH TYPE 1 DIABETES

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People with type 1 diabetes must perform frequent self-management behaviors to maintain glycemic control. Those with higher diabetes distress tend to have worse glycemic control, indicated by higher A1C. Financial stress is common in adults with chronic diseases, but little is known about perceived financial burden in adults with type 1 diabetes or its associations with diabetes distress, self-management behaviors, or A1C. It is also unknown whether diabetes self-efficacy moderates the associations between perceived financial burden or diabetes distress with self-management behaviors.

Surveys were collected from 235 adults with type 1 diabetes. Structural equation modeling tested whether perceived financial burden and diabetes distress were associated with self-management behaviors and A1C; whether performance of self-management behaviors mediated associations between perceived financial burden and diabetes distress with A1C; and whether diabetes self-efficacy moderated associations of perceived financial burden and diabetes distress with self-management behaviors. Education, age, and race/ethnicity were included as covariates. Exploratory analyses assessed correlates of perceived financial burden.

Higher diabetes distress was associated with higher perceived financial burden ($\beta=0.34$, $p<0.001$) and less frequent self-management behaviors ($\beta= -0.74$, $p<0.001$). Lower A1C was associated with more frequent self-management behaviors ($\beta = -0.22$, $p = 0.050$) and higher educational attainment ($\beta = -0.20$, $p = 0.02$). Direct effects of diabetes distress and perceived financial burden on A1C were not significant, nor were indirect effects mediated by self-management behaviors. Diabetes self-efficacy did not moderate associations of perceived financial burden or diabetes distress with self-management behaviors. Higher perceived financial burden was associated with lower income ($p < 0.001$), lower general quality of life ($r = -0.19$, $p = 0.003$), and more chronic complications ($r = 0.19$, $p < 0.01$). Perceived financial burden was highest in uninsured participants ($p = 0.01$); Among insured, those with lower perceived adequacy of insurance reported higher perceived financial burden ($p < 0.001$).

Findings suggest those with higher diabetes distress perform fewer self-management behaviors. Higher perceived financial burden was associated with higher diabetes distress, but its associations with self-management behaviors and A1C were not significant. Longitudinal research is needed in larger samples of adults with type 1 diabetes to explore relations among diabetes distress, perceived financial burden, self-management behaviors, and A1C, as well as identify characteristics that mitigate sources of stress.

Introduction

Type 1 diabetes is a lifelong chronic disease associated with serious complications, including cardiovascular disease, kidney failure, and premature death (Centers for Disease Control and Prevention [CDC], 2014). To reduce the risk of long-term complications, people with type 1 diabetes are recommended to maintain glycemic control as measured by the Hemoglobin A1C (A1C) blood test, a measure of average blood glucose from the previous three months (Diabetes Control and Complications Trial Research Group [DCCT], 1993). However, two thirds of adults with type 1 diabetes do not maintain an A1C less than 7% (Miller et al., 2015) as recommended by the American Diabetes Association (American Diabetes Association [ADA], 2017). Glycemic control is predicted by behavioral and psychological characteristics. Diabetes self-management behaviors include administering insulin and monitoring their blood glucose around the clock (Chiang, Kirkman, Laffel, & Peters, 2014). More frequent self-monitoring of blood glucose predicts lower A1C (Miller et al., 2013). Diabetes distress—the emotional burdens of managing the disease—is common in adults with type 1 diabetes and is associated with worse glycemic control and lower quality of life (Fisher et al., 2015). Specific sources of diabetes distress include feeling powerless, worrying about complications, and feeling burnout from self-management tasks (Fisher et al., 2015).

Little work has explored financial predictors of glycemic control in adults with type 1 diabetes, who require multiple medications and supplies and regular physician visits. Health insurance provides access to care at lower costs, but insurance plans provide variable coverage of diabetes supplies and devices (Burge & Schade, 2014) and the cost of insulin is rapidly increasing (Hua et al., 2016), so these recurrent expenses could be burdensome. Many patients with chronic diseases report financial stress from disease-specific expenses (Tran, Barnes, Montori, Falissard, & Ravaud, 2015). Controlling for actual out-of-pocket medication costs, higher perceived financial burden is associated with lower quality of life and more frequent urgent care visits in adults with asthma (Patel, Caldwell, Song, & Wheeler, 2014). However, it is unknown whether perceived financial burden is associated with diabetes distress, diabetes self-management behaviors, and glycemic control in adults with type 1 diabetes.

In addition to identifying sources of burden or distress associated with worse self-management behaviors and glycemic control, it is important to identify characteristics that buffer against distress (Hilliard, Harris, & Weissberg-Benchell, 2012). For example, self-management behaviors and glycemic control are often better in those with higher diabetes self-efficacy (Johnston-Brooks, Lewis, & Satish, 2002), as those with higher self-efficacy are more likely to set goals, overcome setbacks, and cope with challenges (Bandura, 2004). However, more work is needed to investigate whether the associations between perceived financial burden and diabetes distress with self-management behaviors, depends on how self-efficacious a person is. Using cross-sectional surveys collected from adults with type 1 diabetes between the ages of 26 and 64 years, the objectives of this study were:

Aim 1: Assess the associations among perceived financial burden, diabetes distress, self-management behaviors, and glycemic control (as measured by A1C).

Aim 2: Test whether diabetes self-efficacy moderates the associations between perceived financial burden and diabetes distress with diabetes self-management behaviors.

Exploratory Aim: Describe characteristics associated with perceived financial burden.

Background

Type 1 Diabetes

Twenty-nine million people in the United States have diabetes, a chronic disease in which the body is unable to either produce sufficient insulin or to use insulin effectively (American Diabetes Association [ADA], 2017). Insulin is a hormone necessary for metabolizing glucose, which serves as the body's main source of energy. During digestion, the stomach converts sugars from food into glucose, which is released into the bloodstream. In response to this rapid increase in blood glucose, beta cells in the pancreas secrete insulin, which allows glucose to exit the bloodstream and enter cells, where it can be used for energy. However, due to insulin deficiency, people with diabetes have abnormally high blood glucose, which damages the body's organs and tissues. As a result, people with diabetes are at increased risk of blindness, kidney failure, and cardiovascular disease, making diabetes the seventh leading cause of death in the United States (Centers for Disease Control and Prevention [CDC], 2014).

Most cases of diabetes are categorized as either type 1 diabetes or type 2 diabetes. Type 2 diabetes is the most prevalent type of diabetes, accounting for 90-95% of diabetes cases. Caused by insulin resistance, type 2 diabetes is associated with obesity and older age, and often can be managed with physical activity, healthy diet, or oral medications (CDC, 2014). Five to ten percent of diabetes cases are type 1 diabetes (CDC, 2014). Usually diagnosed in youth (Haller, Atkinson, & Schatz, 2005), type 1 diabetes occurs when the immune system erroneously attacks insulin-producing beta cells in the pancreas, leaving patients unable to produce insulin (Kawasaki, 2014; Yoon & Jun, 2005). There is no known way to prevent or delay the disease, and people with type 1 diabetes must perform frequent, lifelong insulin injections (Chiang et al., 2014). Because people with type 1 diabetes typically have a longer disease duration and incur higher lifetime healthcare costs than those with type 2 diabetes, the economic burden per capita is higher for type 1 diabetes than type 2 diabetes (Tao, Pietropaolo, Atkinson, Schatz, & Taylor, 2010).

Despite significant advancements in type 1 diabetes treatment and outcomes since the discovery of insulin in 1920-21, people with type 1 diabetes are at risk of serious acute and long-term complications from fluctuations and persistent elevation in blood glucose (ADA, 2017). Injecting too much or too little insulin can result in severe hypoglycemia (i.e., very low blood sugar) and diabetic ketoacidosis (i.e., insulin deficiency), acute complications that account for the most deaths among people with type 1 diabetes younger than fifty years of age (Livingstone et al., 2015). Twelve percent of adults with type 1 diabetes report experiencing severe hypoglycemia within the previous six months (Weinstock, Xing, Maahs, et al, 2013), which often results in seizure or loss of consciousness, and can lead to brain and nerve damage (Mohseni, 2014) and death. Five percent of people with type 1 diabetes report having one or more episodes of diabetic ketoacidosis within the previous year (Weinstock et al., 2013), which occurs when blood becomes acidic due to dangerously high blood glucose. In addition to acute complications from glycemic fluctuations, high blood glucose (i.e., hyperglycemia) over time increases patients' risk of long-term complications (CDC, 2014). Cardiovascular disease is the most common long-term complication (Tuomilehto et al., 1998) and accounts for the greatest reduction in life expectancy (Livingstone et al., 2015). Other common long-term complications include blindness, kidney disease, and nerve damage (CDC, 2014).

Acute and long-term complications of type 1 diabetes are costly, both the direct costs of treatment and hospitalization, as well as indirect costs of lost income and reduced life expectancy, altogether costing $14.4 billion annually in the United States (Tao et al., 2010).

Moreover, among people with type 1 diabetes, more frequent or severe complications are associated with lower quality of life (Alvarado-Martel et al., 2015), an individual's perception of their physical, emotional, and social wellbeing (CDC, 2016). For example, quality of life tends to be lower in patients with physical pain from diabetic neuropathy or vision loss from retinopathy (Jacobson et al., 2013). In alignment with the World Health Organization's definition of health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity" (World Health Organization, 1949) scholars and clinicians emphasize the need to promote high quality of life among people with diabetes in addition to optimal medical outcomes (Jones, Vallis, & Pouwer, 2015).

Maintaining glycemic control (A1C<7%) significantly reduces patients' risk of complications, including diabetic ketoacidosis (Weinstock et al., 2013), cardiovascular disease, and premature death (DCCT, 1993). Moreover, better glycemic control is also associated with higher quality of life (Alvarado-Martel et al., 2015) likely because it prevents or delays the onset and development of chronic complications (Jacobson, 2004). Glycemic control is most commonly measured by Hemoglobin A1C (A1C), obtained via a blood test that indicates an individual's average blood glucose over the previous two to three months (Sacks et al., 2011), and the American Diabetes Association (2017) recommends adults with type 1 diabetes maintain an A1C less than 7%. However, less than one third of adults with type 1 diabetes in the United States maintain an A1C within the recommended range (Miller et al., 2015). Therefore, understanding the predictors of glycemic control, including the role of self-management behaviors, is critical.

Diabetes Self-Management Behaviors

Self-management behaviors are strong predictors of glycemic control, accounting for approximately half of the variance in A1C (Gandhi, Vu, Eshtehardi, Wasserman, & Hilliard, 2015; Gonzalez & Schneider, 2011). Administering insulin (via an insulin pump or multiple daily injections) and monitoring blood glucose are key elements of type 1 diabetes self-management. Blood glucose monitoring is the cornerstone of diabetes self-management, and strong evidence shows that more frequent blood glucose monitoring is associated with lower A1C (Miller et al., 2013), as it allows patients to assess whether their blood glucose is within a safe range and treat hypoglycemia or hyperglycemia prior to the onset of acute complications (ADA, 2017). Many patients administer insulin multiple times per day, adjusting insulin doses as needed to account for factors that affect blood glucose: carbohydrates, physical activity, stress, and illness (Chiang et al., 2014). Because consuming carbohydrates increases blood glucose, many people with type 1 diabetes estimate the number of carbohydrates in each meal and attempt to calculate the corresponding dose of insulin (James, Green, Amiel, & Choudhary, 2016). People with type 1 diabetes are recommended to perform regular exercise, which can substantially reduce daily insulin requirements (van Dijk et al., 2016) and provides cardiovascular and psychological health benefits (ADA, 2017), but often causes blood glucose to plummet (Camacho, Galassetti, Davis, & Wasserman, 2005), so patients are recommended to adjust insulin doses and/or consume carbohydrates to prevent exercise-induced hypoglycemia (Colberg, Laan, Dassau, & Kerr, 2015; Riddell & Perkins, 2009). Finally, clinical guidelines recommend people with type 1 diabetes visit their physician two to four times per year to assess glycemic control and screen for potential complications or comorbidities (ADA, 2017).

Type 1 diabetes is a supply- and device-intensive disease to manage (Burge & Schade, 2014). At a minimum, patients need a blood glucose meter, testing strips, lancets, insulin, and needles or syringes. Insulin pumps and continuous glucose monitors are diabetes-specific technologies that can also help people self-manage type 1 diabetes. An insulin pump is a device worn on the body with a cannula inserted under the skin to continuously infuse insulin in more precise doses than injections. Continuous glucose monitors sense internal glucose levels and wirelessly send glucose readings to a portable monitor, which can help people with type 1 diabetes identify overall trends in glycemic fluctuations (Parkin & Davidson, 2009) and detect hypoglycemia or hyperglycemia prior to the onset of severe complications. Insulin pumps and continuous glucose monitors are both associated with notable health benefits—users have lower A1C and lower rates of diabetic ketoacidosis and severe hypoglycemia compared to non-users (Miller et al., 2015; Wong et al., 2014; Battelino et al., 2011).

Socioeconomic characteristics are strong predictors of glycemic control, self-management behaviors, and technology use. For example, A1C is often highest in patients who are non-Hispanic Black/African American (Miller et al., 2015), and those with lower income (Miller et al., 2015) and less education (Strandberg, Grauea, Wentzel-Larsend, Peyrot, & Rokneb, 2014). Socioeconomic characteristics are also associated with the performance of self-management behaviors and use of diabetes technology. For example, frequency of blood glucose monitoring, a key predictor of A1C, is highest among patients with non-Hispanic White race, higher household income, and those with health insurance coverage (Miller et al., 2013). No known study has examined socioeconomic predictors of insulin pump use in adults; however, in youth with type 1 diabetes, insulin pump therapy is more commonly used to treat patients who are White (Willi et al., 2015), and have private health insurance and higher household income (Lin et al., 2013). Continuous glucose monitor use is also more common among those with private health insurance and higher education and household income (Wong et al., 2014). Collectively, these findings suggest that patients' glycemic control and performance of self-management behaviors might depend on whether they can afford the costs of diabetes supplies.

Psychological characteristics such as stress or depressive symptoms also predict self-management behaviors and glycemic control in adults with type 1 diabetes. Even with access to necessary self-management supplies, keeping blood glucose within a safe range requires constant time, effort, and attention (Naranjo, Mulvaney, McGrath, Garnero, & Hood, 2014) and effective problem-solving skills to treat inevitable fluctuations in blood glucose. Considered the ‘quintessential self-managed chronic disease,’ this lifelong intensive treatment puts enormous burden on people with type 1 diabetes (Wiley et al., 2013, p. 1784). Therefore, scholars have explored the sources and consequences of diabetes distress, referring to the emotional burnout and psychological challenges of diabetes, faced by adults with type 1 diabetes.

Diabetes Distress

Chronic diabetes-specific stress, or diabetes distress, is a risk factor for worse health behaviors and outcomes among people with type 1 diabetes (Hilliard et al., 2016). Diabetes distress is defined as emotional burden specific to the disease and its management (Fisher, Gonzalez, & Polonsky, 2014). Distinct from depression, diabetes distress stems from clinical, individual, and contextual factors of managing the disease rather than an underlying mental illness (Esbitt, Tanenbaum, & Gonzalez, 2013). Although diabetes distress has been explored over the last two decades, scholars have only recently explored sources of distress specific to adults with type 1 diabetes. In a qualitative study, adults with type 1 diabetes reported distress from the burden of self-management behaviors, fear of complications, and challenges with the healthcare system (Balfe et al., 2013). In Fisher and colleagues’ study of distress among adults with type 1 diabetes, participants reported feeling powerless over unpredictable changes in blood glucose, being disappointed with their self-management efforts, feeling that their eating behaviors were uncontrolled, and worrying about hypoglycemia and other complications (Fisher et al., 2015). Adults with type 1 diabetes also report distress from feeling that their friends and family are over- or under-involved in their diabetes, being concerned about negative judgments from others, and feeling dissatisfied with their diabetes physician (Fisher et al., 2015).

Diabetes distress is common among adults with type 1 diabetes, but its prevalence varies across demographic or clinical characteristics. Fisher and colleagues found that, in a sample of adults with type 1 diabetes, forty-one percent had at least moderate diabetes distress (Fisher et al., 2015). Diabetes distress is generally higher in women as well as those with younger age, more diabetes complications, and longer diabetes duration (Fisher et al., 2015; Sturt et al., 2015; Lašaitė, Ostrauskas, Žalinkevičius, Jurgevičienė, & Radzevičienė, 2016). Lašaitė and colleagues found that women, particularly those diagnosed with type 1 diabetes as children, had higher distress than men or those diagnosed as adults, suggesting a potential interaction between gender and disease duration in predicting diabetes distress (Lašaitė et al., 2016). Joensen and colleagues (2013) found that adults living without a partner have higher distress, lower quality of life, and higher A1C than those living with a partner, and the negative impact of living alone was especially true for women (Joensen, Almdalb, & Willainga, 2013). Specific sources of distress also seem to depend on demographic or clinical factors. For example, adults with higher body mass index (BMI ≥ 25 kg/m^2) have reported higher distress specific to food and eating (e.g., “thoughts of food and eating control my life”) compared to those with low BMI (Fisher et al., 2015). Additionally, hypoglycemia-related distress is higher among non-White patients and those without a partner (Fisher et al., 2015).

Higher diabetes distress is associated with more depressive symptoms (Powers, Richter, Ackard, & Craft, 2017; Schmitt et al., 2015), and worse glycemic control in adults with type 1 diabetes (Fisher et al., 2015; Powers et al., 2017; Strandberg et al., 2014; Zoffmann, Vistisen, & Due-Christensen, 2014). Evidence suggests that higher diabetes distress might lead to worse glycemic control both directly and indirectly. Chronic stress causes increased cortisol production and thus greater insulin resistance and higher blood glucose (Lloyd, Smith, & Weinger, 2005), which would explain a direct influence of diabetes distress on A1C. Additionally, those with higher diabetes distress tend to perform less physical activity (Lloyd, Pambianco, & Orchard, 2010), suggesting diabetes distress might negatively influence the performance of self-management behaviors (Lloyd, Smith, & Weinger, 2005; Hilliard, Yi-Frazier, Hessler, Butler, Anderson, & Jaser, 2016), thus indirectly affecting A1C

Emerging evidence suggests that diabetes distress is responsive to intervention and is a modifiable predictor of glycemic control. For example, two recent interventions (one using cognitive behavioral therapy, the other using mindfulness-based group therapy) significantly reduced diabetes distress and depressive symptoms in participants with type 1 and type 2 diabetes, yet A1C did not change (van Son et al., 2013; Tovote et al., 2014). In adults with type 1 diabetes, an empowerment-based intervention—which incorporated discussions of goal setting, decision making, and coping into a diabetes self-management education program—significantly increased participants' self-efficacy and decreased participants' diabetes distress and A1C (Hermanns, Kulzer, Ehrmann, Bergis-Jurgan, & Haak, 2013). However, more work is needed to identify factors influencing the associations among diabetes distress, self-management behaviors, and glycemic control (Sturt et al., 2015). Missing from the diabetes distress literature is research exploring financial burden in adults with type 1 diabetes. Because people with type 1 diabetes require frequent doctor visits and a large toolkit of supplies (e.g., insulin, testing strips, needles or insulin pump) to effectively manage their condition, these recurrent costs might be stressful.

However, it is unknown whether financial burden is associated diabetes distress, self-management behaviors, glycemic control, or general quality of life.

Financial Burden

In the United States, people with type 1 diabetes incur nearly $10,000 in annual medical expenditures, with most direct costs attributable to hospital inpatient visits and prescription drugs or medical supplies such as insulin, testing strips, and insulin pumps (Tao et al., 2010). The proportion of these costs paid out-of-pocket by patients depends on their health insurance coverage. Among adults aged 18-64 years living in the United States in 2015, nine percent were uninsured, but 67% held private health insurance and 37% held public health insurance within the previous twelve months (Barnett & Vornovitsky, 2016). Although health insurance coverage increases access to care at lower costs, many insurance companies and employers rely on cost sharing for medication and healthcare services (Paez, Zhao, & Hwang, 2009), passing more of the expenses onto patients. Compared with those without chronic diseases, adults with chronic diseases incur significantly higher out-of-pocket healthcare costs due to recurrent expenses of necessary medications, supplies, and services (Paez et al., 2009). The cost of insulin—a necessity for people with type 1 diabetes—has skyrocketed in recent years and, unlike traditional medication, has no low-cost generic form or over-the-counter substitute medicine available at a lower cost (Hua et al., 2016). Moreover, insurance companies provide variable coverage of diabetes supplies and technology (Burge & Schade, 2014). Therefore, out-of-pocket costs might be especially high for adults with type 1 diabetes.

Higher medication cost sharing and higher out-of-pocket costs are associated with lower medication adherence for many patients with chronic diseases (Eaddy, Cook, O'Day, Burch, & Cantrell, 2012). Adults with lower income are especially at risk of cost-related non-adherence to medication (Galbraith et al., 2011). Among low-income adults with private health insurance, those with higher plan deductibles reported significantly fewer visits to primary care doctors and specialists compared to those in no-deductible plans (Rabin, Jetty, Petterson, Saqr, & Froehlich, 2017). However, patients with high household incomes also engage in cost-related non-adherence to medication (Piette, Beard, Rosland, & Mchorney, 2011), suggesting patients' perception of financial burden, not just the actual costs, predicts health behaviors and outcomes (Patel et al., 2014).

Perceived financial burden is common among patients with chronic diseases. In a qualitative study exploring treatment burden among adults with chronic diseases across thirty-four countries, respondents reported time, energy, and emotional difficulties of managing their disease; one-fifth (21%) of respondents mentioned stress from high costs of medication, doctor visits, and blood tests (Tran et al., 2015). Financial burdens of healthcare expenses interfered with some participants' ability to effectively manage their disease and obtain necessary healthcare, and some participants reported having to save up for medication and having to strictly budget to afford basic bills, leaving no money for leisure expenses (Tran et al., 2015). In another qualitative study assessing economic hardship in adults with chronic diseases, some patients reported being unable to afford necessary medication; having to decide between buying medication and food or paying other bills; or needing to borrow money from friends and family (Jeon, Essue, Jan, Wells, & Whitworth, 2009). Other participants were able to purchase necessary medication, but struggled to afford additional costs of maintaining a healthy lifestyle (e.g., healthy food or gym memberships), or had to compromise other interests (e.g., vacations, hobbies) to prioritize medication costs (Jeon, Essue, Jan, Wells, & Whitworth, 2009). These findings highlight the need to consider patients' perception of economic hardship and its influence on their quality of life, rather than measuring financial burden solely as a function of costs and income.

Building on this qualitative work, Patel and colleagues (2014) examined perceived financial burden—defined as being unable to afford medical bills, or paying bills despite financial hardship—in adults with asthma (Patel et al., 2014). Perceived financial burden was positively associated with out-of-pocket medication costs. After controlling for out-of-pocket costs, participants with higher perceived financial burden reported lower quality of life and more frequent urgent care visits for their asthma in the previous twelve months (Patel et al., 2014). This work suggests patients' health and quality of life might be associated with perceived financial burden rather than the actual out-of-pocket healthcare costs (Patel et al., 2014).

Limited work has explored perceived financial burden among adults with type 1 diabetes. In qualitative studies with adults with type 1 diabetes, participants reported stress from the financial strain from diabetes-related expenses (Tanenbaum, & Gonzalez, 2012) and frustrations with navigating the healthcare system, such as struggling to obtain coverage for diabetes technologies (Balfe et al., 2013). In the second Diabetes Attitudes, Wishes, and Needs (DAWN-2) survey, completed by eight thousand people across seventeen countries with either type 1 or type 2 diabetes, 44% of participants reported that their diabetes somewhat or very negatively impacted their financial situation, and 45% indicated that they have had trouble paying for their diabetes medications (Nicolucci et al., 2013). Although this emerging evidence suggests financial burden might be a common stressor for adults with type 1 diabetes, it is unknown how perceived financial burden is related to diabetes distress, self-management behaviors, glycemic control, or quality of life. Further, little work has considered whether positive factors, like diabetes self-efficacy, provide a buffer against diabetes distress and perceived financial burden for adults with type 1 diabetes.

Diabetes Self-Efficacy

Self-efficacy predicts the adoption and maintenance of many healthy behaviors, including physical activity, healthy eating, and medication adherence (Schwarzer et al., 2007). Defined as an individual's belief in their ability to change their behavior or exert control over their environment (Bandura, 1997), those with higher self-efficacy are more likely to set goals for their health behaviors, expect better outcomes in response to their behavior change, and stay motivated to pursue their goals despite facing obstacles (Bandura, 2004). People with higher self-efficacy also tend to experience less stress and fewer negative emotions than those with lower self-efficacy (Bandura, 1997). Importantly, self-efficacy is dynamic and can be increased by interventions that teach self-regulation, goal setting, and coping skills (Bandura, 2004).

Effectively managing type 1 diabetes requires lifelong commitment and personal responsibility for performing frequent, complex self-management behaviors (Pallayova & Taheri, 2014), so previous studies have explored diabetes-specific self-efficacy and its associations with self-management behaviors and glycemic control. Several types of diabetes-specific self-efficacy have been explored, including: self-efficacy for performing specific diabetes self-management behaviors, such as checking blood sugar, exercising two to three times per week, and detecting hypoglycemia and hyperglycemia (Van Der Ven et al., 2003); general perceived competence in their ability to manage diabetes and control blood glucose (Williams, McGregor, King, Nelson, & Glasgow, 2005); and psychosocial diabetes self-efficacy—also known as diabetes empowerment—referring to perceived ability to recognize dissatisfaction with diabetes care, set and achieve goals, seek social support, and cope with diabetes-specific stress (Anderson, Funnell, Fitzgerald, & Marrero, 2000). Self-efficacy for performing specific behaviors, general perceived competence, and psychosocial self-efficacy have all shown positive associations with self-management behaviors and glycemic control among adults with type 1 diabetes (Sacco & Bykowski, 2010; Johnston-Brooks et al., 2002; Wallston, Rothman, & Cherrington, 2007; Zoffmann et al., 2014; Hermanns et al., 2013).

In addition to predicting better self-management behaviors and glycemic control, self-efficacy might provide a buffer against distress for people with type 1 diabetes (Hilliard et al., 2012). In cross-sectional studies, adults with type 1 diabetes with higher perceived competence for managing diabetes report lower diabetes distress (Mohn et al., 2015; Zoffmann et al., 2014). Moreover, a recent intervention effectively increased self-efficacy in adults with type 1 diabetes, which resulted in lower diabetes distress and better glycemic control (Hermanns et al., 2013). However, few studies have explored whether the strength of association between diabetes distress and self-management behaviors depends on how self-efficacious a person is. Given that people with higher self-efficacy tend to better cope with stress and recover from setbacks (Bandura, 2004), it is possible that those with higher diabetes self-efficacy have better self-management behaviors and glycemic control, regardless of fluctuations in diabetes distress or perceived financial burden. In contrast, those with lower diabetes self-efficacy are predicted to have worse self-management behaviors and glycemic control that are contingent on fluctuations in diabetes distress or perceived financial burden. Thus, interventions might be especially effective in reducing distress—and improving self-management behaviors and glycemic control—by bolstering diabetes self-efficacy. The objective of this study is to assess how perceived financial burden and diabetes distress, as well as their interactions with self-efficacy, are associated with self-management behaviors and glycemic control among adults with type 1 diabetes.

Conceptual Model

The conceptual model is informed by the Diabetes Resilience Model, which posits that the interplay between demographic, psychosocial, and behavioral factors predicts whether a person with type 1 diabetes realizes positive health outcomes—namely, low A1C and high quality of life (Hilliard et al., 2012). According to this framework, more frequent performance of self-management behaviors is the proximal predictor of positive health outcomes, including low A1C. Risks and assets are defined as characteristics that can negatively or positively influence self-management behaviors and glycemic control. The Diabetes Resilience Model also proposes that diabetes-specific protective processes or characteristics influence the relationship between risks/assets and diabetes self-management behaviors. These diabetes-specific protective processes are hypothesized to build on one's assets to buffer risk, thus enhancing self-management behaviors and improving glycemic control and quality of life (Hilliard et al., 2012).

Certain pathways in the Diabetes Resilience Model are well supported by the literature. For example, strong evidence demonstrates that patients who perform more frequent self-management behaviors have better glycemic control as indicated by lower A1C (Gonzalez & Schneider, 2011; Miller et al., 2013). Additionally, many individual characteristics (i.e., risks and assets) are associated with self-management behaviors and glycemic control. For example, self-management behaviors and glycemic control are often worse in those with lower socioeconomic status (Miller et al., 2015) and higher diabetes distress (Fisher et al., 2015). Chronic stress, including diabetes-specific stress, can affect blood glucose through several mechanisms. Physiologically, the neuroendocrine system secretes cortisol in response to stress, which influences glucose metabolism and results in higher blood glucose (Lloyd, Smith, & Weinger, 2005). Additionally, stress can interfere with the ability to perform self-management behaviors

(Lloyd et al; Hilliard et al., 2016). Thus, the Diabetes Resilience Model predicts risk factors (e.g., diabetes distress) influence glycemic control both directly as well as indirectly via self-management behaviors (Hilliard et al., 2012).

Less work has tested interactions between diabetes-specific protective processes and risk factors as proposed by the Diabetes Resilience Model, with most evidence in samples of children or adolescents. For example, self-efficacy moderates the relationship between diabetes-specific family conflict with frequency of blood glucose monitoring and glycemic control among youth with type 1 diabetes (Noser, Huffhines, Clements, & Patton, 2016). Among adolescents, coping strategies have been shown to mediate the relationship between diabetes-related stress and quality of life (Jaser, Patel, Xu, Tamborlane, & Grey, 2017). In another study with emerging adults with type 1 diabetes, diabetes-specific self-efficacy partially mediated the relationship between impulse control and diabetes self-management, suggesting self-efficacy might be especially important among those with low impulse control (Stupiansky, Hanna, Slaven, Weaver, & Fortenberry, 2012). For adults with type 1 diabetes, effective coping skills are important, especially for those with high anxiety (Sultan, Epel, Sachon, Vaillant, & Hartemann-Heurtier, 2008).

Although evidence suggests diabetes-specific protective processes might influence the relationship between risk factors and diabetes self-management behaviors, more work is needed in adults with type 1 diabetes, given that high diabetes distress and poor glycemic control is common in this population. The purpose of this study is to explore perceived financial burden as a risk factor for worse self-management behaviors and health outcomes in adults. The conceptual framework, adapted from the Diabetes Resilience Model, is shown in Figure 1. The hypothesized model proposes that diabetes distress and perceived financial burden are risk factors associated with worse self-management behaviors and glycemic control, and diabetes self-efficacy is a diabetes-specific protective factor that moderates the associations of diabetes distress and perceived financial burden with self-management behaviors. Consistent with the Diabetes Resilience Model (Hilliard et al., 2012), it is hypothesized that those with higher diabetes self-efficacy, despite encountering challenges with diabetes distress and perceived financial burden, will perform more frequent self-management behaviors and achieve lower A1C than those with lower self-efficacy.

Aims and Hypotheses

Aim 1: Assess the associations among perceived financial burden, diabetes distress, self-management behaviors, and glycemic control (as measured by A1C).

Hypothesis 1: Perceived financial burden is positively associated with diabetes distress.

Hypothesis 2: Higher perceived financial burden is associated with a) less frequent performance of self-management behaviors and b) higher A1C.

Hypothesis 3: Higher diabetes distress is associated with a) less frequent performance of self-management behaviors and b) higher A1C.

Hypothesis 4: More frequent performance of diabetes self-management behaviors is associated with lower A1C.

Hypothesis 5: Diabetes self-management behaviors partially mediate the association between perceived financial burden and A1C.

Hypothesis 6: Diabetes self-management behaviors partially mediate the association between diabetes distress and A1C.

Aim 2: Test whether diabetes self-efficacy moderates the associations between perceived financial burden and diabetes distress with diabetes self-management behaviors.

Hypothesis 7: The association between perceived financial burden and diabetes self-management behaviors is stronger when diabetes self-efficacy is lower.

Hypothesis 8: The association between diabetes distress and diabetes self-management behaviors is stronger when diabetes self-efficacy is lower.

Exploratory Aim: Describe characteristics associated with perceived financial burden.

Methods

Participant Eligibility

Inclusion criteria. Patients eligible for the study were adults with type 1 diabetes between ages 26 and 64 years, a period when patients are generally financially independent and are responsible for their own diabetes self-management tasks. Eligible participants received care at Virginia Commonwealth University (VCU) Health for any reason, at any inpatient or outpatient department, within the previous twenty-four months (i.e., between October 2015 and September 2017). All survey materials were written in English, so only patients able to read English could participate in the study.

Exclusion criteria. Patients younger than 26 years were excluded, as youth might be enrolled on their parents' health insurance and might not be financially independent, influencing their perceived financial burden of diabetes. Adults aged 65 years and older were excluded as these patients are eligible for Medicare, potentially influencing their perceived financial burden of diabetes. Because severe psychiatric conditions (e.g., thought disorders or psychosis) often interfere with patients' ability to self-manage their disease and maintain glycemic control (ADA, 2017), patients were excluded from the study if they had a diagnosis of any of the following conditions in their electronic medical record: major depression with psychotic symptoms; bipolar disorder with psychotic symptoms; or schizophrenia, schizotypal, delusional, and other nonmood psychotic disorders.

Participant Identification

Virginia Commonwealth University Institutional Review Board approved the study, including a Partial Waiver of Authorization for Recruitment in order to identify eligible participants via Protected Health Information in electronic medical records. Clinical Research Informatics Group at VCU Center for Clinical and Translational Research was provided with inclusion and exclusion criteria, both ICD-10 diagnostic codes and demographic characteristics. Clinical Research Informatics identified patients between ages 26-64 years with type 1 diabetes who received care at any VCU Health location between October 2015 and September 2017, excluding those with psychotic symptoms, schizophrenia, or other thought disorders listed in their electronic medical chart.

Clinical Research Informatics identified 899 patients who met eligibility criteria, and extracted the following information for each patient: first and last name, date of birth, current age, street address, email address, medical record number, telephone number, and the date(s) and department(s) where patient received care at VCU Health between October 2015 and September 2017. Ages ranged from 26 to 64 years (*M*=44.5, *SD*=11.3). Email addresses were available for 380 of 899 patients.

Study Design

Cross-sectional surveys were collected using a mixed-mode, five-contact approach. The survey implementation procedures were informed by the Tailored Designed Method for mixed-mode surveys (Dillman et al., 2014). Specifically, the following strategies of the Tailored Design Method were implemented, which consistently increase survey response rates: maximizing benefits, minimizing costs, and incorporating trust-inducing elements; sending participants multiple coordinated contacts; providing incentives to participate, and using multiple modes for contacting participants and collecting responses.

According to Dillman and colleagues (2014), people are more likely to complete surveys when they believe the benefits to be high, costs to be low, and when the source is deemed trustworthy. Direct benefits of participating in a survey are often low but people feel satisfaction when helping others, especially when they can provide unique, valuable input (Dillman et al., 2014). Therefore, as suggested by Dillman and colleagues (2014), letters and emails asked participants for their help and expressed appreciation for their time and input. The following strategies recommended by Dillman and colleagues (2014) for gaining participant trust were also used: Correspondence sent to participants was personalized, explained how their contact information was obtained, and included the researcher's contact information so participants could ask questions or opt out of participating in the survey. Letters were sent on official university stationary and were signed in blue ink. Because token incentives are shown to significantly increase survey response rates (Dillman et al., 2014), a $1 bill was enclosed with the initial letter, and respondents were entered into a drawing for an iPad. Finally, multiple coordinated contacts were sent to participants over several months, a key element of the Tailored Design Method shown to increase survey response rates (Dillman et al., 2014).

Procedure

Two modes—mail and internet, were used to contact participants and collect survey responses. All eligible participants were contacted up to five times by mail or email. The mode and timing of contacts differed between people with versus without an email address in their electronic medical record. Participants with both an email address and a mailing address in their electronic medical record—referred to as the email condition—were contacted by both email and postal mail. Participants without an email address in their electronic medical record—referred to as the mail condition—received all contacts by postal mail. Surveys were collected both online and through paper-and-pencil questionnaires, with the goal of collecting as many online survey responses as possible from participants in both conditions before sending paper-and-pencil surveys to non-respondents. Study data were collected and managed using REDCap, a HIPAA-secure, web-based method for data collection and storage hosted at Virginia Commonwealth University (Harris, Taylor, Thielke, Payne, Gonzalez, & Conde, 2009). Online surveys were completed on the REDCap website. Paper-and-pencil surveys were labeled with the participant's unique study identification number, and responses were manually entered into REDCap.

Email condition. Participants with both an email address and mailing address in their electronic medical record (*n*=380) were contacted up to five times—two via postal mail, three via email. On day 1, participants were sent a letter describing the purpose of the study, explaining how the participant's contact information was obtained, and requesting participants complete an online survey by accessing the REDCap URL and entering a unique access code. A $1 bill was enclosed with the initial letter as a token of appreciation. On day 7, an email was sent to participants, reminding them of the letter that was recently sent and providing them with a clickable link to the online REDCap survey. On day 12, non-respondents were sent another email with a link to the online survey. On day 22, non-respondents were sent a survey packet via postal mail, which included a cover letter, consent form, paper-and-pencil questionnaire, and pre-paid postage return envelope. On day 42, a final email reminder with a survey link was sent to non-respondents. Letters and emails sent to participants are also shown in Appendix A.

Mail condition. Participants without an email address (*n*=419) in their electronic medical record received up to five contacts by postal mail. On day 1, participants were sent the same letter and instructions as the initial contact in the email condition. The letter also provided participants with the REDCap URL, unique access code, and an enclosed $1 bill. On day 7, a postcard was mailed to participants, which thanked those who had responded and asked those who had not responded to please do so. To ensure sensitive information was not visible to those other than the intended recipient, the postcard did not include the study's details, URL, or access code. Instead, the postcard stated that participants could call the provided phone number to request a replacement letter if they had misplaced instructions for completing the survey. On day 21, non-respondents were sent a reminder letter containing the URL and access code. Three weeks later (day 35), non-respondents were mailed a paper-and-pencil questionnaire with an enclosed cover letter, consent form, and postage-paid return envelope. On day 54, a final reminder letter was sent to non-respondents. Appendix C also shows letters that were sent to participants in the mail condition.

Incomplete web surveys. Online survey participants had the option to save and return to the survey later. If participants selected the "save and return later" button, REDCap provided them with a unique validation code, different from the unique access code, to return to their partially completed survey. Partial respondents to the online survey, in both the mail and email condition, continued to receive follow-up letters or emails in the same timeline as non-respondents.

Informed Consent

The consent form was posted on the first page of the online survey and a printed consent form was enclosed with the paper-and-pencil survey (shown in Appendix B). For participants who completed the online survey, advancing to the next page indicated consent to participate in the study. For participants who completed the paper-and-pencil survey, a printed consent form was enclosed with the mailed survey and returning the paper-and-pencil questionnaire indicated consent to participate.

In addition to collecting survey responses, participants were asked whether they authorized study staff to access A1C test results in their VCU Health electronic medical chart from the previous twenty-four months and to link these results with their survey responses. The consent form stated that participants could complete the survey without consenting to the release of A1C results from medical chart data, and that all survey respondents could enter the iPad Air drawing regardless of whether they authorize the release of this information. On the last page of the mail and online surveys, participants were asked whether they authorize (yes/no) the release of the date(s) and result(s) of A1C tests from their VCU Health electronic medical chart within the last twenty-four months. Selecting *yes* to this item indicated consent for the release of their A1C test results.

Measures

Surveys, which are shown in Appendix C, included the following measures:

Demographics and health information. Demographic questions included age, gender, race/ethnicity, employment status, marital status, household size, education, household income, health insurance coverage and type, and height and weight to calculate body mass index (BMI). Health questions included current form of insulin delivery (insulin pump vs. multiple daily injections), current use of a continuous glucose monitor (yes/no), and diagnosis age (to calculate diabetes duration).

Diabetes complications and comorbidities. Participants were asked if they have ever been diagnosed (yes/no) with the eight most common chronic complications and comorbidities among adults with type 1 diabetes in the second cross-national Diabetes Attitudes, Wishes, and

Needs (DAWN2) survey: sleeping problems, eye damage, depression, nerve damage, sexual dysfunction, foot ulcers, kidney disease, and heart disease (Nicolucci et al., 2013). The total number of chronic complications and comorbidities was computed for each respondent. Four questions assessed participants' history of severe hypoglycemia and diabetic ketoacidosis, two acute complications of type 1 diabetes. Participants were asked "Have you ever experienced seizure or loss of consciousness from low blood sugar (hypoglycemia)?" and "Have you ever had diabetic ketoacidosis diagnosed by a doctor that required treatment at a healthcare facility?" to measure severe hypoglycemia and diabetic ketoacidosis, respectively—and participants responded yes/no to each question. Participants also reported how many times they had experienced severe hypoglycemia and diabetic ketoacidosis in the last 12 months. These definitions were used by Weinstock and colleagues' questionnaire assessing history of severe hypoglycemia and diabetic ketoacidosis in people with type 1 diabetes (Weinstock et al., 2013). Recall of significant and often infrequent health events like hospitalizations and emergency department visits are highly correlated with medical records (Cabana et al., 2006).

Glycemic control. Participants were asked to self-report the date (month/year) and result (%) of their last A1C test, which assesses a patient's average blood sugar level over the previous two to three months (Sacks et al., 2011). Higher A1C scores indicate worse glycemic control. Although self-report A1C was the primary outcome measure for all participants, the date(s) and result(s) of A1C tests were also collected from electronic medical records. Among participants who had an A1C result in their chart and consented for us to access this, the correlation between self-report A1C and electronic medical record A1C was calculated to assess accuracy of self-report A1C within the sample.

Diabetes distress. Diabetes distress was measured using the Type 1 Diabetes Distress

Scale (Fisher et al., 2015), which contains twenty-eight items measuring seven subscales of distress: powerlessness, eating distress, management distress, hypoglycemia distress, negative social perceptions, friend/family distress, and physician-related distress. Participants indicated how much of a problem each item is, responding on a six-point scale ranging from *not a problem* to *a very serious problem*. The average response for each subscale was calculated, with higher scores indicating higher diabetes distress. The scale has shown high internal consistency (a=0.91) and significant associations with A1C (r=0.17) in adults with type 1 diabetes (Fisher et al., 2015).

Diabetes self-efficacy. Diabetes self-efficacy was measured with the 8-item Diabetes Empowerment Scale-Short Form (Anderson et al., 2003), which assesses participants' perceived ability to set and achieve goals, recognize dissatisfaction and readiness to change, and manage psychosocial aspects of diabetes. Items include "In general, I believe that I… 'know the positive ways I cope with diabetes-related stress' and 'am able to turn my diabetes goals into a workable plan." Participants responded to each item on a five-point scale ranging from *strongly disagree* to *strongly agree*, with higher scores representing higher diabetes self-efficacy. This measure has good reliability (a=0.85).

Diabetes self-management behaviors. The Diabetes Self-Management Questionnaire includes sixteen items within five subscales: glucose management, insulin administration, dietary control, physical activity, and healthcare use (Schmitt et al., 2013). Respondents indicated the extent to which each item applies to their self-care behaviors performed over the previous eight weeks, on a four-point scale ranging from *does not apply to me* to *very much applies to me*. The scale has good internal consistency (a=0.84) and scores are associated with lower A1C (r=-0.53) for adults with type 1 diabetes (Schmitt et al., 2013). Average scores were computed for each subscale, with higher scores indicating more frequent performance of self-management behaviors.

Perceived financial burden. Because no known validated scale has been developed to measure perceived financial burden in adults with type 1 diabetes, perceived financial burden was measured using four items that were adapted from two established measures of perceived financial burden: three items adapted from Caregiver Reaction Assessment (Nijboer, Triemstraa, Tempelaar, Sanderman, & Van Den Bos, 1999), and one item adapted from a recent study of perceived financial burden among adults with asthma (Patel et al., 2014). One item from the DAWN Impact of Diabetes Profile (Nicolucci et al., 2013) was included, and two additional items were also developed to measure perceived financial burden.

Financial strain from diabetes. A modified version of the financial subscale of the Caregiver Reaction Assessment (Nijboer et al., 1999) was used to assess financial strain of diabetes. The three items included "Caring for my partner puts a financial strain on me." For this study, 'partner' was replaced with 'diabetes.' Response options range from *strongly disagree* to *strongly agree* (a=0.83; Nijboer et al., 1999). Higher scores represent higher financial burden.

Problematic costs of diabetes. One item was modified from Patel and colleagues (2014) study of perceived financial burden among adults with asthma. In their study, participants were asked about perceived financial burden using the single question, "Do you consider cost to be a problem in managing your asthma?" Response options ranged from *not a problem* to *a very serious problem* (Patel et al., 2014). For this study, the item was modified by replacing 'asthma' with 'diabetes' and using a similar question and answer format as the Caregiver Reaction Assessment items. Therefore, participants were asked to rate their agreement with the item "Cost is a problem in managing my diabetes," responding on a five-point scale ranging from *strongly* *disagree* to *strongly agree*. A higher score represents higher financial burden.

Underuse of diabetes supplies and healthcare services. Two additional items were developed to measure perceived financial burden: “Because of costs, I underuse diabetes supplies” and “Because of costs, I go to the doctor less frequently than I should.” Participants responded to these items on a five-point scale ranging from strongly disagree to strongly agree.

DAWN Impact of Diabetes Profile. One item was selected from the DAWN Impact of Diabetes Profile (Nicolucci et al., 2013), which asks participants how diabetes impacts their financial situation on a seven-point scale. Response options range from *very positively* to *very negatively* and higher scores represent higher financial burden of diabetes.

Descriptive and exploratory measures of perceived financial burden. Additional items were included to explore potential factors associated with perceived financial burden.

Out-of-pocket costs for diabetes supplies. Participants were presented with a list of six common diabetes supplies and devices (insulin, testing strips, needles or syringes, insulin pump supplies, continuous glucose monitor supplies, and glucagon) and were asked whether (yes/no) they purchased the item in the last twelve months. If yes, participants estimated a) how many times they spent money out-of-pocket on the medication/supplies in the last twelve months, and b) how much they paid out of pocket each time. Participants’ annual out-of-pocket costs for each item was computed by multiplying the out-of-pocket cost by the number of times the item was purchased. Using a similar approach to measure out-of-pocket costs of recurrent medication incurred by adults with asthma, Patel and colleagues found that higher out-of-pocket medication costs were associated with higher perceived financial burden, lower quality of life, and more frequent urgent care visits for asthma (Patel et al., 2014).

Perceived adequacy of health insurance. Participants with health insurance were asked to rate the adequacy of their health insurance plan using four items from the National Survey of Children with Special Health Care Needs (Bramlett et al., 2014), which surveys parents or guardians of children with special healthcare needs about the adequacy of their child's health insurance plan. Participants are asked whether their health insurance 1) offers benefits that meet your needs, 2) allows you to see the healthcare providers you need, and 3) whether the costs not covered by your health insurance are reasonable. For those three items, participants respond on a four-point scale ranging from *never* to *always*. A fourth question asks participants whether they would change to a different health insurance plan given the chance, responding on a four-point scale ranging from *definitely yes* to *definitely not*. The instructions were modified in the current study so that participants rated their own health insurance plan rather than their child's.

General quality of life. The five-item World Health Organization (WHO-5) Well-Being Index (Bech, Gudex, & Johansen, 1996) is a widely used measure of general quality of life (Topp, Østergaard, Søndergaard, & Bech, 2015). Five statements ask participants to indicate how they have felt over the previous two weeks (e.g., I have felt cheerful and in good spirits), responding on a six-point scale ranging from *at no time* to *all of time*. Responses are summed and then multiplied by four to create a total score ranging from 0 to 100, with higher scores representing better general quality of life. In adults with type 1 diabetes, the WHO-5 has shown high internal consistency (a=0.91), and significant correlations with depressive symptoms (r=0.69, p<.001) and diabetes distress (r=-0.62, p<.001), supporting the reliability and validity of the WHO-5 as a measure of general quality of life (Hajos, Pouwer, Skovlund, et al., 2013).

Survey Development and Pretesting

The measures scales described in the previous section widely range in recall periods: from two weeks, one month, eight weeks, and twelve months. However, it is recommended that self-administered questionnaires limit the variation in question formats and instructions as much as possible to avoid confusing respondents (Fowler, 2009). To reduce question complexity, some measures were modified so that the questionnaire used only two recall periods: one month and twelve months. For quality of life, diabetes distress, and diabetes self-management measures, a one-month recall period was selected because the timeframe is the middle of the three recall periods in the original measures. A twelve-month recall period was used for measuring out-of-pocket costs and frequency of acute complications because acute complications are often infrequent and because some participants might only purchase medication or supplies several times per year. In the survey instructions, timeframe changes were emphasized in bold font.

Next, the REDCap and paper-and-pencil surveys were created. The Tailored Design Method recommends grouping similar items and response formats, as well as beginning the survey with questions that are interesting and easy to answer (Dillman et al., 2014). Therefore, the survey began with measures of diabetes self-management behaviors, quality of life, and diabetes distress—each of which used a recall period of one month—and concluded with demographic questions. After creating the survey, a convenience sample of eight adults with type 1 diabetes pretested the online and paper-and-pencil surveys and commented on the clarity of the questions, response options, survey formatting. In response to their feedback, minor wording changes were made to some items and instructions, and the formatting was revised to ensure the survey pages were easy to view across a range of computers and mobile devices. Five more adults with type 1 diabetes pretested the revised survey prior to beginning data collection.

Data Analytic Plan

Preliminary Data Analysis. Descriptive analyses were conducted using SPSS 24. The sample was described using frequency and percent of categorical variables (e.g., gender, ethnicity, insulin treatment method) and the mean and standard deviation of continuous variables (e.g., age, diabetes duration). Pearson's correlations, independent samples t-tests, and one-way ANOVAs were used to calculate correlations among constructs and differences in self-report A1C between demographic groups. The percent of missing data was examined for each variable.

The correlation between self-report and electronic medical record A1C was calculated for participants with both values available. Because many participants had received care at a specialty clinic at VCU Health (e.g., ophthalmology, surgery), and because their most recent visit to VCU Health was up to two years prior to taking the survey, the correlation between self-report A1C and electronic medical record A1C was also computed in the subset of people whose self-report A1C was within three months of the A1C in their electronic medical record. The goal of calculating the correlation in this subset was to exclude participants who might have received their most recent A1C test at a healthcare facility outside of VCU Health, allowing for some leeway in participant recall of the specific month.

Structural Equation Modeling. Hypotheses were tested with structural equation modeling, which is advantageous for testing complex models with multiple predictors, mediators, moderators, and outcome variables (Gunzler, Chen, Wu, & Zhang, 2012). Structural equation modeling allows the interpretation and estimation of models containing both observed (i.e., manifest) and unobserved (i.e., latent) variables (Gunzler, Chen, Wu, & Zhang, 2012). Because latent variables cannot be directly observed, thus introducing measurement error (Schofield, 2015), failing to account for measurement error in latent constructs can result in biased statistical estimates. Structural equation modeling, however, accounts for measurement error of latent constructs, which produces less biased statistical estimates of associations among latent variables (Kline, 2011). Most variables in the model are latent constructs: perceived financial burden, diabetes distress, self-efficacy, and self-management behaviors. Glycemic control is considered an observed variable because it is measured with the A1C blood test.

R software with Latent Variable Analysis (*lavaan*) package (Rosseel, 2012) was used to conduct the two steps of structural equation modeling: 1) assessing the measurement model to ensure that survey items (i.e., indicators) adequately measure the latent constructs; and 2) assessing the structural model, which tests the proposed relationships among latent constructs (Kline, 2011). Because several constructs were measured using ordinal type variables, confirmatory factor analysis was conducted using diagonally weighted least squares ("WLSMV"), a robust estimator that can model categorical or ordered data because it does not assume normally distributed variables (Brown, 2006; Li, 2016). However, because this estimator uses listwise deletion of missing values, only participants who provided a self-report A1C result were included in the analysis.

Measurement model. First, the measurement model of latent constructs (i.e., confirmatory factor analysis) was assessed to determine how well the latent constructs are measured by their indicators (Kline, 2011). As discussed in the measures section, the survey included eight indicators of diabetes self-efficacy and seven indicators of perceived financial burden. The five subscales of the Diabetes Self-Management Questionnaire and the seven subscales of the Type 1 Diabetes Distress Scale were indicators of self-management behaviors and diabetes distress, respectively. Given that latent constructs should have at least two—but preferably three to five indicators—the survey included enough indicators for each latent construct (Kline, 2011).

The factor loading of the first indicator of each latent construct was constrained to 1, which sets the observed variables on the same scale as the latent variables (Kline, 2011). A confirmatory factor analysis is said to have a good fit if the Chi Square test is non-significant; the Comparative Fit Index (CFI) and Tucker Lewis Index (TLI) are greater than 0.95; and the Root Mean Squared Error of Approximation (RMSEA) is less than 0.05, and Squared Root Mean Square Residual (SRMR) is less than 0.08 (Kline, 2011). In addition to assessing these model fit indices, standardized factor loadings of each indicator with its latent construct were examined. Items with low standardized factor loadings (r<0.2) were removed from the model and the confirmatory factor analysis was re-run (Kline, 2011). If the CFI and TLI increase and/or the RMSEA and SRMR decrease after removing these items, results suggest the model is improved by removing those items (Kline, 2011).

Structural models. Next, the hypothesized relationships among latent constructs, known as the structural model, were assessed (Kline, 2011). In structural equation modeling, rectangles depict observed variables and ellipses depict latent variables. Single-headed straight arrows indicate a theoretical causal relationship or direct effect from one variable to another. Variables that are predicted by another variable in the model (i.e., arrow pointing toward it) are considered endogenous, whereas exogenous variables are not predicted by any other variable in the model. Double-headed arrows indicate covariance terms between exogenous variables and correlated errors between endogenous error terms.

The first structural model, which assessed Aim 1, included two endogenous variables (glycemic control and self-management behaviors) and two exogenous variables (diabetes distress and perceived financial burden). The covariance term between diabetes distress and perceived financial burden indicates a hypothesized correlation between these constructs. Three covariates were added to the model as predictors of A1C: age, academic education, and race/ethnicity. Coefficients and p-values were assessed for all hypothesized direct effects, using a significance level of 0.05 to test each hypothesis. Hypothesis 1 was tested by assessing the covariance between perceived financial burden and diabetes distress. The significance of the direct effects of perceived financial burden on diabetes self-management behaviors (hypothesis 2a) and A1C (hypothesis 2b), as well as the direct effects of diabetes distress on diabetes self-management behaviors (hypothesis 3a) and A1C (hypothesis 3b) were examined. The direct effect of diabetes self-management behaviors on A1C was examined to test hypothesis 4. To test mediation proposed in hypotheses 5 and 6, the nonparametric percentile bootstrap was used to estimate 95% confidence intervals for the indirect effects of perceived financial burden on A1C (hypothesis 5) and the indirect effect of diabetes distress on A1C (hypothesis 6), each mediated by self-management behaviors.

The second structural model, which assessed Aim 2, tested whether diabetes self-efficacy moderates the associations between perceived financial burden and diabetes distress with diabetes self-management behaviors. Three items from each construct (perceived financial burden, diabetes self-efficacy, and diabetes distress) were used to compute interaction terms using double mean centered unconstrained approach (Marsh, Wen, Hau, Little, Bovaird, & Widaman, 2007). Hypotheses 7 and 8 tested the direct effects of the perceived financial burden x diabetes self-efficacy interaction, and the diabetes distress x diabetes self-efficacy interaction, on diabetes self-management behaviors.

Exploratory Analysis. The exploratory aim was to describe characteristics associated with perceived financial burden. Using SPSS 24, Pearson’s correlations were calculated to test whether perceived financial burden is associated with participants’ annual out-of-pocket costs for diabetes supplies, general quality of life, and perceived adequacy of health insurance. Independent samples t-tests assessed whether perceived financial burden differs between participants who received free or discounted diabetes supplies (yes/no), have discussed costs with their healthcare provider (yes/no), and have spent money out-of-pocket (yes/no) on diabetes supplies in the last twelve months. One-way ANOVAs tested whether perceived financial burden is associated with participants' health insurance coverage (uninsured vs. public insurance vs. private insurance), employment status (employed vs. not employed), and marital status (single vs. married vs. divorced/separated or widowed). A significance level of 0.05 was used for all statistical tests.

Power and Sample Size

Structural equation modeling requires large sample sizes to adequately estimate associations among all variables. As model complexity increases (i.e., more variables, constructs, and pathways are added), sample size requirements also increase (Kline, 2011). In this study, there were seven indicators of perceived financial burden, seven indicators of diabetes distress, five indicators of diabetes self-management behaviors, eight indicators of diabetes self-efficacy, one observed variable measuring glycemic control (A1C), and three covariates (education, age, and race/ethnicity) for a total of thirty-one variables that might be included in the model. A minimum recommended sample for structural equation modeling is five times the number of indicators (Bentler & Chou, 1987). Thus, the goal was to recruit a sample size as large as possible, with a minimum of 155, which is equal to five times the number of potential indicators.

Results

Of the 899 potential participants, 380 (42%) were in the email condition, and 419 (58%) were in the mail condition. During data collection, 133 participants (15%) were removed from the contact list for the following reasons: fifty-eight had non-deliverable mailing addresses, nine opted out of participating, seventeen were deceased, two were severely disabled, thirty had type

2 diabetes, ten did not have diabetes, and seven had received a kidney-pancreas transplant and thus no longer used insulin.

Letters and emails to participants were sent between October 2017 and December 2017, and survey responses were collected between October 2017 and January 2018. Twenty-seven percent of participants completed the survey (*n*=241). Of the 380 participants in the email condition, 137 (36%) responded: 113 responded online, 24 completed paper-and-pencil questionnaires. Twenty percent of participants in the mail condition responded (*n*=104, 20%): 48 responded online, 56 completed paper-and-pencil questionnaires. Six responses were removed for the following reasons: four respondents noted that most questions were not applicable as they had previously received a kidney-pancreas transplant and/or did not take insulin; one survey was blank; and one was completed by participant's mother, who noted that her adult child was cognitively impaired. The data analyzed and reported in subsequent sections refers to the remaining 235 (26%) responses.

Sample Characteristics

The most common department in which respondents were treated at VCU Health were outpatient general medicine (*n*=87, 37.0%), outpatient endocrinology (*n*=20, 8.5%), outpatient ophthalmology (*n*=11, 4.7%), and outpatient family medicine (*n*=9, 3.8%). The remaining 46% of respondents received treatment from other inpatient or outpatient services, including surgery, radiology, emergency services, nephrology, and cardiology. The average respondent age was 44.7 years (*SD*=10.8) and more than half (*n*=135, 57.4%) were women. Most participants were non-Hispanic White/Caucasian (*n*=147, 62.6%) or non-Hispanic Black/African American (*n*=73, 31.1%). A quarter of respondents had completed high school or less (*n*=60, 25.5%), one third had attended some college or received an associate's degree (*n*=77, 32.8%), and forty-one percent held a bachelor's degree or higher (*n*=98, 41.7%). Annual household income was less than $25,000 for one third of respondents (*n*=80, 34.0%) and greater than $100,000 for fourteen percent (*n*=33, 14.0%). Half of respondents were married or cohabitating (*n*=116, 49.6%), and half were currently employed (*n*=122, 51.9%). Respondents' demographic information is also shown in Table 2.

Health and diabetes information of the participants are shown in Table 3. Average age at type 1 diabetes diagnosis was 20.6 years (*SD*=13.0) and diabetes duration ranged from less than one year to sixty years (*M*=23.8 years, *SD*=13.1). Most participants treated their diabetes using multiple daily injections (*n*=145, 61.7%). Respondents had been diagnosed with an average of 2.1 (*SD*=1.9) chronic complications or comorbidities, the most common of which were depression (*n*=101, 43.0%), neuropathy (*n*=89, 37.9%), and retinopathy (*n*=82, 34.9%). Half of respondents had ever experienced severe hypoglycemia resulting in seizure or loss of consciousness (*n*= 119, 50.9%), and almost forty percent had ever experienced diabetic ketoacidosis that was treated at a healthcare facility (*n*=88, 37.6%). In the last twelve months, 22% and 14% of respondents had experienced one or more episodes of severe hypoglycemia or diabetic ketoacidosis, respectively. Eighty-nine percent (*n*=209) of respondents self-reported the result of their most recent A1C test, which ranged from 4.9% to 15.0%; average self-reported A1C was 8.0% (*SD*=1.7), and 30% reported their most recent A1C was less than 7.0%. Self-report A1C had the most missing data of any variable (11%); less than three percent of data was missing for all other variables.

Tables 4 and 5 show bivariate associations between self-report A1C result, demographic characteristics, and model constructs (average scores of observed indicators). As shown in these tables, self-report A1C was higher in participants with higher diabetes distress, higher perceived financial burden, and more total chronic complications; and was lower in participants with higher diabetes self-management behaviors, higher diabetes self-efficacy, and higher income and education (all *p-values*<0.05). As shown in Table 5, self-report A1C was significantly higher in participants using multiple daily injections than those using an insulin pump (Mean Difference=8.4% vs. 7.5%, $F_{1,202}$=14.4, *p*<0.001), but was not associated with employment status, gender, BMI, age, or diabetes duration. Table 6 presents the mean, range, and reliabilities of the scales and subscales used to measure diabetes distress, diabetes self-management behaviors, diabetes self-efficacy, and general quality of life.

Electronic Medical Record A1C Results

Of 235 respondents, 213 (90.6%) authorized the release of their A1C test result(s) from their electronic medical record, and 129 (61% of those who consented) had a test result available. The most recent A1C test result in these participants' electronic medical record ranged from 4.9% to 17.3% (*M*=8.84, *SD*=2.63). The oldest A1C test in the electronic medical record was from October 2015 and the most recent was in December 2017. On average, participants' self-reported most recent A1C was 3.1 months prior to survey completion date. One hundred thirteen participants had both a self-report and electronic medical record A1C test result available; of these participants, self-report A1C was significantly correlated with those in the electronic medical record (*r*=0.71, *p*<0.001, *n*=113). Self-report A1C values, on average, were 0.69% lower than the electronic medical record value. On average, participants reported that their most recent A1C test was five months later than the date of the most recent A1C test shown in their electronic medical record. Fifty-seven respondents' self-reported most recent A1C test was within three months of A1C test in their electronic medical record; among this subset, the correlation between the two A1C values was 0.84 (*p*<0.001). On average, self-report A1C value was 0.47% lower than the electronic medical record A1C for these 57 respondents (*SD* of the difference: 1.28, Median difference: 0.00).

Measurement Model

Confirmatory factor analysis assessed the measurement model of the latent constructs and their indicators: diabetes distress (7 indicators), perceived financial burden (7 indicators), diabetes self-management behaviors (5 indicators), and diabetes self-efficacy (8 indicators). In the robust estimates of model fit, the Chi-Square test was significant ($p<0.001$) and the CFI and TLI were 0.90 and 0.89, respectively. The RMSEA was 0.07 and the SRMR was 0.09. All items loaded significantly onto their factors, but five items were removed because of low standardized factor loadings: one indicator of diabetes self-management behaviors (healthcare use subscale), one indicator of diabetes distress (friend/family distress subscale), one indicator of diabetes self-efficacy ("I know what parts of diabetes care I am dissatisfied with"), and two indicators of perceived financial burden ("My resources are adequate to care for my diabetes" and "How does diabetes impact your financial situation?"). After removing these items and re-running the confirmatory factor analysis, the Chi-Square test was significant; the CFI and TLI were 0.93 and 0.92, respectively; and the RMSEA and SRMR were both 0.07. Because model fit indices improved after removing these items, the revised model was used for testing the structural model. Fit indices and factor loadings of the revised structural model are also shown in Table 7.

Structural Models

The first structural model tested hypotheses 1 through 6 and included the following constructs: perceived financial burden, diabetes distress, diabetes self-management behaviors, and glycemic control. Education, age, and race/ethnicity (White vs. non-White) were included as covariates. Results are summarized in Table 8. The covariance between diabetes distress and perceived financial burden was significant, supporting hypothesis 1. Diabetes distress was significantly associated with self-management behaviors (β=-0.743, p<0.001), supporting hypothesis 2a, but the direct effect of diabetes distress on A1C (hypothesis 2b) was not significant. Direct effects of perceived financial burden on diabetes self-management behaviors (hypothesis 3a) and A1C (hypothesis 3b) were not significant. Hypothesis 4 was supported as higher diabetes self-management was associated with lower A1C (β=-0.219, p=0.050). The indirect effects of diabetes distress and perceived financial burden on A1C, mediated by diabetes self-management behaviors, were not significant. Thus, data did not support hypotheses 5 and 6 that diabetes self-management behaviors partially mediate the effects of diabetes distress and perceived financial burden on A1C. Of the covariates, higher education was associated with lower A1C (p=0.019), but race/ethnicity and age were not significant predictors of A1C. Model fit indices of the first structural model were: CFI=0.92, TLI=0.90, RMSEA=0.08, SRMR=0.08; χ^2=321.8, p<0.001.

In the second structural model, which tested hypotheses 7 and 8, two interactions were added to the model with direct effects on diabetes self-management behaviors: diabetes self-efficacy x diabetes distress, and diabetes self-efficacy x perceived financial burden. As shown in Table 9, neither interaction term significantly predicted diabetes self-management behaviors, so hypotheses 7 and 8 were not supported. As in the first structural model, diabetes distress had a significant direct effect on diabetes self-management behaviors (p<0.001); higher self-management behaviors (p=0.046) and higher education (p=0.018) were each associated with lower A1C. Model fit indices were: CFI= 0.91, TLI= 0.89, RMSEA= 0.06; SRMR=0.07; χ^2=478.4, p<0.001.

Exploratory Analysis

Exploratory analyses examined characteristics associated with perceived financial burden. Results are shown in Tables 10-13. Higher perceived financial burden was associated with lower household income (r=-0.30, p<0.001) and lower general quality of life (r=-0.19, p=0.003). Perceived financial burden was higher in participants who reported discussing diabetes costs with their healthcare provider in the last twelve months, compared to those who did not (M=3.37 vs 2.67, t_{229}= -4.69, p<.001), but perceived financial burden did not differ between people who did vs. did not receive free or discounted diabetes supplies. Marital status, race/ethnicity, household size, and employment status were not associated with perceived financial burden. Perceived financial burden differed by insurance coverage ($F_{2,231}$=7.70, p=0.001). Post-hoc pairwise comparisons revealed that perceived financial burden was higher in uninsured participants than in those with public health insurance (Mean Difference= 0.59, SE=0.20, p=0.01) or private health insurance (Mean Difference=0.69, SE=0.18, p=0.01); the difference between public and private was not significant (Mean Difference=-0.09, SE=0.17, p=0.86). Among participants with health insurance, higher perceived financial burden was associated with lower perceived adequacy in the insurance company's benefits and services (r=-0.42, p<0.001), available health care providers (r=-0.44, p<0.001), and cost coverage (r=-0.41, p<0.001), and higher likelihood of switching to a different health insurance plan given the chance (r=-0.39, p<0.001).

As shown in table 12, two-thirds of respondents reported spending money out-of-pocket on insulin and testing strips in the last twelve-months; of these participants, average annual out-of-pocket costs were $776 and $621, respectively. Insulin pump supplies and continuous glucose monitor supplies were the most expensive items, totaling $1248 and $1407 in annual out-of-pocket expenses, respectively. However, less than a quarter of respondents reported spending out-of-pocket money on these supplies in the last twelve months. Perceived financial burden was higher in people who spent money out-of-pocket on insulin, test strips, and needles in the last twelve months compared to those who did not spend money out-of-pocket on these supplies (*p-values*<0.05); however, perceived financial burden was not significantly different between people who did versus did not incur out-of-pocket costs for insulin pump supplies, continuous glucose monitor supplies, or glucagon, in the last twelve months (shown in table 13).

Discussion

This study investigated factors associated with diabetes self-management behaviors and glycemic control in adults with type 1 diabetes. Hypotheses were informed by the Diabetes Resilience Model, which provides a framework for understanding the interplay between risk factors and protective processes in influencing the performance of self-management behaviors and the achievement of optimal glycemic control in people with type 1 diabetes (Hilliard et al., 2012). Extending the Diabetes Resilience Model to adults with type 1 diabetes, surveys were collected from a diverse sample of 235 adults with type 1 diabetes to assess the associations among diabetes distress, perceived financial burden, diabetes self-efficacy, engagement in self-management behaviors, and glycemic control. Consistent with the Diabetes Resilience Model, diabetes distress and perceived financial burden were considered risk factors that are negatively associated with diabetes self-management behaviors and glycemic control (Hilliard et al., 2012. Diabetes self-efficacy was also assessed as a protective characteristic, as the Diabetes Resilience Model posits that these positive processes might buffer against risk factors for worse health behaviors and outcomes (Hilliard et al., 2012). Thus, higher diabetes self-efficacy was expected to weaken the associations between diabetes distress and perceived financial burden with self-management behaviors.

Aim 1: Diabetes Distress and Perceived Financial Burden

Aim 1 explored diabetes distress, defined as the emotional burden of managing diabetes (Fisher, Gonzalez, & Polonsky, 2014). Researchers have explored diabetes distress over the last several decades, but only recently investigated sources of diabetes distress specific to adults with type 1 diabetes, resulting in the development of the Type 1 Diabetes Distress Scale (Fisher et al, 2015). Fisher and colleagues found that forty-percent of adults with type 1 diabetes reported at least moderate diabetes distress, and that higher diabetes distress in adults with type 1 diabetes (indicated by higher scores on the Type 1 Diabetes Distress Scale) is associated with higher A1C, indicating worse glycemic control (Fisher et al., 2015). Scholars have suggested two potential mechanisms that could explain the association between diabetes distress and glycemic control: First, diabetes distress could directly affect A1C due to physiological effects of chronic stress on hyperglycemia; Second, those with emotional burnout from diabetes distress might engage in self-management behaviors less frequently, which in turn leads to higher A1C (Lloyd, Smith, & Weinger, 2005; Hilliard et al., 2016). However, little research has examined direct and indirect mechanisms linking diabetes distress and glycemic control (Sturt et al., 2015).

The direct effect of diabetes distress on A1C was not significant in the first structural model. Instead, higher A1C was significantly associated with less frequent performance of self-management behaviors and lower attained education. These findings align with several pathways proposed by the Diabetes Resilience Model: first, that self-management behaviors are a significant, proximal predictor of A1C; second, that socioeconomic characteristics are risks or assets associated with A1C. Because higher education was associated with lower A1C after controlling for diabetes self-management behaviors, those with higher academic education might have more resources to support their diabetes care that help them achieve better glycemic control. Given significant associations between education, income, employment, and health insurance coverage, data suggest people with higher education might have greater access to healthcare services and diabetes supplies and devices that contribute to better glycemic control (Miller et al., 2015; Wong et al., 2014; Battelino et al., 2011).

Participants with higher distress reported less frequent performance of self-management behaviors, as reported in the structural model. Thus, findings suggest emotional burnout and psychological challenges of diabetes management might interfere with patients' engagement in self-care activities, including blood glucose monitoring, insulin administration, physical activity, and healthy diet. The highest sources of distress reported by participants were powerlessness, eating distress, and management distress. These findings highlight the psychosocial challenges of living with a chronic disease requiring constant and demanding self-management behaviors that can lead to costly or debilitating complications. Given the association between diabetes distress and self-management behaviors, future research is warranted to further explore sources of diabetes distress in adults with type 1 diabetes, and develop interventions to reduce distress in efforts to motivate more frequent self-management. Previous interventions have targeted depressive symptoms in adults with type 1 diabetes with mindfulness training and cognitive behavioral therapy, aiming to reduce stress and depressive symptoms and improve coping skills (Amsberg, Anderbro, Wredling, et al., 2009; van Son et al., 2013; Tovote et al., 2014). In addition to developing and implementing such interventions, screening for diabetes distress might be useful for clinical care of adults with type 1 diabetes, to assist healthcare providers in identifying and targeting psychosocial barriers to diabetes self-management behaviors.

Despite higher diabetes distress being associated with less frequent self-management behaviors, and the association between less frequent self-management behaviors and higher

A1C, the indirect effect of diabetes distress on A1C (mediated by self-management behaviors) was non-significant. Thus, no significant evidence was found to suggest that engagement in self-management behaviors explains a link between diabetes distress and glycemic control. It is possible that other mediators or moderators could explain how diabetes distress relates to A1C. It is also possible that the non-significant indirect effect is due to the strength of association between self-management behaviors and A1C, which narrowly met the criteria for statistical significance with a p-value of 0.05. Because some subscales of the Diabetes Self-Management Questionnaire had low reliability (shown in Table 6), and one subscale was removed from the measurement model because of its low standardized factor loading, the Diabetes Self-Management Questionnaire might not have been reliable enough as a mediator to detect this indirect effect. Thus, refining and developing measures of diabetes self-management behaviors are needed to better understand the associations among diabetes distress, self-management behaviors, and glycemic control.

The current study is among the first to explore perceived financial burden in adults with type 1 diabetes, which was also assessed in Aim 1. In previous qualitative studies, adults with type 1 diabetes report financial stress from out-of-pocket expenses required for diabetes-specific supplies, medication, and healthcare services. In other chronic diseases, such as asthma, higher perceived financial burden is associated with more urgent care visits and worse quality of life (Patel et al., 2014). Yet, no known study assessed perceived financial burden and its associations with self-management behaviors and glycemic control in adults with type 1 diabetes. In the present study, perceived financial burden was conceptualized as the psychological or emotional burdens from diabetes expenses. Because no existing scales measure perceived financial burden in adults with type 1 diabetes, items were modified from other measures assessing financial strain in patients with cancer or asthma, and two additional items were developed to assess self-reported underuse of supplies or healthcare services because of high cost. Perceived financial burden was hypothesized to be correlated with diabetes distress, as both constructs are related to psychological or emotional burden/stress. Like diabetes distress, higher perceived financial burden was hypothesized to be associated with less frequent performance of self-management behaviors and higher A1C, and the association between perceived financial burden and A1C was expected to be partially mediated by self-management behaviors.

Also reported in the results of the first structural model, higher perceived financial burden was correlated with higher diabetes distress; however, perceived financial burden was not significantly associated with self-management behaviors or glycemic control in the structural models. The significant association between perceived financial burden and diabetes distress suggests that perceived financial burden might be a risk factor for worse self-management behaviors or glycemic control in adults with type 1 diabetes; however, these associations are not significant after controlling for diabetes distress. Cronbach's alpha was 0.87 for the five items of perceived financial burden used in the structural model, indicating good reliability. However, it is possible that the experience of perceived financial burden for people with type 1 diabetes was not fully captured in the five selected items. For example, some items referred to direct costs of diabetes supplies or healthcare visits, but other direct or indirect costs of type 1 diabetes could also be burdensome and stressful (e.g., costs from missed work or school, treatment supplies for treatment non-severe hypoglycemia). Future mixed-methods studies are needed to further explore the experience of perceived financial burden in adults with type 1 diabetes, as well as to develop and refine valid, reliable measures of perceived financial burden.

Aim 2: Diabetes Self-Efficacy

The second aim of the study was to test whether the associations between diabetes distress and perceived financial burden with self-management behaviors are weaker in participants with higher diabetes self-efficacy. The Diabetes Resilience Model argues that identifying such protective processes is equally as important as investigating risk factors for worse self-management behaviors or glycemic control (Hilliard, Harris, & Weissberg-Benchell, 2012). Interventions can promote protective processes that buffer against specific risk factors to equip people with type 1 diabetes with skills and resources to cope with stress and overcome barriers to diabetes self-management (Hilliard, Harris, & Weissberg-Benchell, 2012). Consistent with the Diabetes Resilience Model, diabetes self-efficacy was explored as a protective process that buffers against diabetes distress and perceived financial burden. Diabetes self-efficacy was measured using the Diabetes Empowerment Scale-Short Form, which assesses psychosocial self-efficacy for diabetes management: perceived ability to recognize need to change, set and achieve goals, and cope with diabetes-specific stress (Anderson et al., 2003). Because psychosocial self-efficacy assesses general ability to set goals, cope with stress, and enlist social support, it was hypothesized that those with higher diabetes self-efficacy could cope or overcome stress from diabetes distress or financial burden and continue to engage in self-management tasks, thus weakening the associations between these risk factors and self-management behaviors.

As reported in the second structural model results, higher diabetes self-efficacy did not moderate the associations of either diabetes distress or perceived financial burden with diabetes self-management behaviors. Thus, there was no evidence that diabetes self-efficacy buffers against the effects of diabetes distress and perceived financial burden on diabetes self-management behaviors in this sample. In cross-sectional studies, adults with type 1 diabetes with higher perceived competence for managing diabetes report lower diabetes distress (Mohn et al., 2015; Zoffmann et al., 2014). Moreover, a recent intervention incorporated self-efficacy and empowerment into a diabetes self-management education program, which combined practical diabetes management skills with discussions of coping, social support, and goal setting; diabetes distress and A1C decreased in adults with type 1 diabetes who participated in this intervention (Hermanns et al., 2013). It is possible that increasing self-efficacy might reduce distress and improve glycemic control in a longitudinal study, but in cross-sectional studies, the strength of association between distress and self-management behaviors might not depend on how self-efficacious a person is. It is also possible that positive characteristics other than diabetes self-efficacy are buffers against diabetes distress or perceived financial burden. Researchers have identified other positive psychological characteristics associated with better self-management and A1C in youth with type 1 diabetes, such as hope or optimism; family or social support; or internal locus of control (Joyce et al., 2012). More work is needed in adults with type 1 diabetes to identify positive characteristics associated with effective self-management behaviors and optimal glycemic control. Perhaps some positive characteristics buffer against specific types of stress, but only for certain people (i.e., depends on gender, marital status, employment status, income). Identifying risk factors for worse self-management behaviors and glycemic control, as well as potential protective processes for each risk factor, is needed to inform future interventions that can empower adults with type 1 diabetes to self-manage their disease and realize positive health outcomes.

Exploratory Analysis of Perceived Financial Burden

Exploratory findings in this study shed light on the experience of perceived financial burden in adults with type 1 diabetes and its associations with demographic, financial, and health characteristics. Half of respondents *agreed* or *strongly agreed* that cost is a problem in managing their diabetes, and 57% reported difficulty in paying for things necessary for treating diabetes. Forty-eight percent of respondents said that diabetes either somewhat negatively or very negatively impacts their financial situation, similar to the 44% of people with diabetes in the DAWN-2 study who reported that diabetes either very negatively or somewhat negatively impacts their financial situation (Nicolucci et al., 2013). Not only is perceived financial burden common in this sample, results suggest perceived financial burden influences participants' treatment decision making and health care seeking behavior. Specifically, 35% of respondents agreed that they underuse supplies or insulin because of costs, and 22% said they go to the doctor less than they should. Given that more blood glucose self-monitoring is associated with lower A1C (Miller et al., 2013), and that insulin is necessary for treating hyperglycemia, underusing either of these supplies could result in chronically high A1C and thus higher risk of chronic complications. Rationing insulin due to costs could quickly lead to diabetic ketoacidosis (a life-threatening acute complication) and death.

Building on previous qualitative data, findings of this study provide novel insight to characteristics associated with perceived financial burden. Previous qualitative work suggests perceived financial burden affects people at all incomes: Some people have to choose between food and medical bills, whereas others feel burdened by costs that could otherwise be spent on hobbies or leisure activity (Jeon, Essue, Jan, Wells, & Whitworth, 2009). In respondents of the current study, correlations were observed between higher perceived financial burden, lower income, higher A1C, and more chronic complications or comorbidities, consistent with previous work showing racial and socioeconomic disparities in glycemic control and diabetes outcomes (Miller et al., 2015; Grauea, Wentzel-Larsend, Peyrot, & Rokneb, 2014). Given the toolkit of supplies and devices and regular healthcare services required for managing type 1 diabetes, it is not surprising that the diabetes expenses could be stressful for anyone, but especially burdensome to those with lower incomes. Although perceived financial burden was not associated with self-management behaviors or glycemic control in the structural model, more work is needed to explore these associations over time to assess what impact, if any, underusing supplies or feeling financial strain has on diabetes self-management behaviors and outcomes. It is possible that those with higher perceived financial burden are unable to purchase necessary supplies for checking their blood glucose and administering insulin, thus leading to worse self-management behaviors and worse glycemic control, and ultimately more complications. Complications could also result in higher healthcare costs and thus higher perceived financial burden. Thus, longitudinal research is necessary to explore predictors and outcomes of perceived financial burden in adults with type 1 diabetes.

Higher perceived financial burden and worse glycemic control were also associated with lower general quality of life, an important outcome for people with diabetes, independent of medical outcomes (Jones, Vallis, & Pouwer, 2015). Measured using the WHO-5 measure of general quality of life, participants rated their subjective wellbeing, including positive mood, vitality, and general interest in life activities (Bech, Gudex, & Johansen, 1996). Quality of life was higher in participants with lower A1C and fewer complications. Complications from diabetes (e.g., neuropathy, retinopathy) can cause pain, limited mobility, and impaired vision, which might impact energy and mood, thus lowering general quality of life. However, in a study in adolescents with type 1 diabetes, lower quality of life predicted subsequent decline in self-management behaviors and glycemic control (Hilliard, Mann, Peugh, & Hood, 2013), suggesting quality of life can serve as both an outcome and a predictor of glycemic control. More work is needed in adults with type 1 diabetes to understand how quality of life impacts, and is impacted by, diabetes management and health outcomes. Perceived financial burden, which may not be associated with general quality of life in youth, might contribute to general quality of life in adults with type 1 diabetes. Adults with asthma who report more frequent emergency department visits and incur higher out-of-pocket medical expenses, also report lower quality of life (Patel et al., 2014). Extending this work to adults with type 1 diabetes, financial burden could be considered as a potential variable that influences the association between quality of life and glycemic control.

In addition to measuring perceived financial burden, several questions assessed out-of-pocket costs of diabetes supplies because higher out-of-pocket costs are associated with lower medication adherence for people with chronic diseases (Eaddy, Cook, O'Day, Burch, & Cantrell, 2012) but little work has explored out-of-pocket costs incurred by adults with type 1 diabetes or how this relates to financial stress. Participants were asked to estimate out-of-pocket costs spent on diabetes supplies in the last twelve months. Because recall bias is a known limitation of self-report measures of medication cost (Patel et al., 2014; Paez, Zhao, & Hwang, 2009), these data are considered exploratory estimates of out-of-pocket costs with some inaccuracy assumed. The most commonly reported expenses were for insulin and test strips, both critical for the two key elements of diabetes self-management: blood glucose self-monitoring and insulin administration. For both supplies, perceived financial burden was higher in those who spent money out-of-pocket than those who did not, suggesting a moderate association between perceived financial burden and out-of-pocket costs for medication or supplies. High out-of-pocket costs are likely associated with higher perceived financial burden, but the strength of this association might depend on patients' demographic (e.g., income) or psychological (e.g., coping) characteristics. Future studies could further assess the association between perceived financial burden and actual out-of-pocket costs, and the associations of each measure with glycemic control.

Perceived financial burden also varied by health insurance coverage. Uninsured respondents reported higher perceived financial burden than those with public or private insurance, likely because those who are uninsured are responsible for paying full price for healthcare visits and diabetes costs. Among those with health insurance, perceived financial burden did not differ between those with public versus private insurance, but was associated with the individual's perceived adequacy of the specific insurance plan. Each insurance plan varies in its coverage of diabetes supplies and services, influencing total out-of-pocket costs incurred (Burge & Schade, 2014). Four survey questions measured perceived insurance adequacy, including benefits, providers, cost coverage, and general satisfaction. For all four questions, lower adequacy was associated with higher perceived financial burden. Findings suggest that having health insurance is necessary but not sufficient for lowering financial burden of diabetes; instead, adequacy of each plan must be considered, as the insurance plan's drug formulary, physician network, and cost-sharing provisions influence healthcare use and performance of diabetes management behaviors.

Perceived financial burden did not differ between respondents using an insulin pump versus those who use multiple daily injections. Insulin pumps provide continuous delivery of insulin and allow more precise insulin doses than injections, and insulin pump users often have better glycemic control than those using injections (Miller et al., 2015). Indeed, insulin pump users in this sample reported significantly lower A1C than those using multiple daily injections. Despite clear health benefits of insulin pumps, the device and their supplies are more expensive than needles and syringes used to administer multiple daily injections. Health insurance generally reimburses some or most of the cost of insulin pump supplies, but cost-sharing varies by policy. Depending on the deductible and co-insurance for durable medical equipment, out-of-pocket costs for insulin pump supplies can be expensive (Burge & Schade, 2014). Respondents' self-reported annual out-of-pocket costs were $1248 on average for insulin pump supplies compared with $318 for needles or syringes, but insulin pump users also reported higher household income than multiple daily injection users. Because perceived financial burden was higher in those with lower income, and income was significantly higher in insulin pump users than multiple daily injection users, data suggest those who incurred the highest out-of-pocket costs might not have reported high perceived financial burden because they were the most well off financially.

This study did not investigate reasons why participants used an insulin pump or multiple daily injections to treat their diabetes. Most research examining insulin pump use and the transition from injections to an insulin pump, are with youth with type 1 diabetes. Insulin pumps are commonly used to treat youth with type 1 diabetes who are White (Willi et al., 2015), have private health insurance, and higher household income (Lin et al., 2013). Although most cases of type 1 diabetes are diagnosed by age 18, one quarter of people with type 1 diabetes are diagnosed as adults (Haller, Atkinson, & Schatz, 2005). In respondents of this study, average age at diagnosis was twenty years, and half of participants were older than age 18 when diagnosed. More research is needed to understand predictors of insulin pump transition in adults. It is possible that those with higher income are more likely to use insulin pump than multiple daily injections because they can financially support the out of pocket costs and have adequate health insurance coverage, allowing them to reap the benefits of insulin pump use (e.g., lower A1C, higher quality of life). However, income and insurance coverage can fluctuate over time, which could influence treatment decisions. Further disentangling the impact of insurance coverage and income on treatment decisions and ultimate health outcomes, could elucidate the mechanisms in which socioeconomic characteristics influence type 1 diabetes outcomes.

One third of participants reported discussing out-of-pocket costs with their healthcare provider. In a qualitative study exploring physician perspectives of patients' financial burden, many physicians expressed that patients' out-of-pocket costs were a barrier to chronic disease management and were important to address (Patel, Shah, & Shallcross, 2015). However, physicians in the study reported: difficulty identifying which patients struggle with financial burden, discomfort with discussing finance with patients, little time to discuss costs in the clinic visit, and lack of financial solutions to provide patients. Instead, physicians suggested ancillary care providers, such as care managers, were more skilled and set-up to address financial barriers with patients; screening forms were also suggested to better flag patients' financial barriers to diabetes management (Patel, Shah, & Shallcross, 2015).

About a quarter (27%) of survey respondents reported receiving free or discounted diabetes supplies in the last twelve months. Several sources of financial assistance could help patients with type 1 diabetes afford their supplies. For example, most pharmaceutical companies offer financial assistance programs that reduce or eliminate patients' out-of-pocket costs for supplies and medications. More research is needed to assess whether people with type 1 diabetes are aware of such programs, and to test whether patient enrollment in financial assistance programs reduces perceived financial burden and improves self-management behaviors and glycemic control. In addition to standardized screening for financial barriers in patients with type 1 diabetes, health systems and physician practices might benefit from implementing standardized protocol to refer patients to eligible programs, with dedicated care managers who can help patients navigate their insurance and reduce out-of-pocket costs.

In addition to policy and health system-level changes that could affect affordability and access to care, it is possible that psychosocial interventions could also be useful in reducing perceived financial burden in adults with type 1 diabetes. For example, embedding relevant financial information into a diabetes education or empowerment program could equip participants with knowledge regarding budgeting, navigating insurance plans, and identifying financial assistance programs; these in turn might which might help people with type 1 diabetes reduce out-of-pocket costs and financial strain from diabetes expenses. As posited by the Diabetes Resilience Model, equipping people with type 1 diabetes with effective coping and problem-solving skills could buffer against risk factors for worse self-management and glycemic control, thus empowering people to achieve positive health outcomes despite facing distress or financial burden (Hilliard et al., 2012). Development and evaluation of such interventions is needed to determine how to reduce perceived financial burden in adults with type 1 diabetes, and to test whether reducing perceived financial burden leads to improvements in self-management behaviors and glycemic control.

Measurement of Glycemic Control

The primary study outcome was glycemic control, which was measured through participants' self-reported result of their most recent A1C blood test. Self-report measurements allow for larger sample sizes and potentially wider generalizable of results, than restricting eligibility to participants with a recent A1C test in their electronic medical record. Indeed, nearly ninety percent of respondents provided a self-report A1C value in the survey, whereas only half of respondents had one available in the electronic medical record. Average self-reported A1C among respondents was 8.0 (*SD*=1.7) and 30% reported their most recent A1C was less than 7%, consistent with national estimates that only one-third of adults with type 1 diabetes achieve A1C less than 7% (Miller et al., 2015) as recommended by the American Diabetes Association (2015). Self-report measures are subject to inaccuracies due to recall bias or social desirability, yet little work has explored accuracy of self-report A1C in adults with type 1 diabetes. Thus, respondents were offered the option to release A1C results from the last twenty-four months from their electronic medical record. Ninety percent of respondents authorized the release of their A1C test(s); sixty percent of respondents had one or more results available.

In participants with both a self-report and electronic medical records A1C available, these values were highly correlated (r=0.71), but self-reported values were on average 0.69% lower than the electronic medical record. However, many participants had large discrepancy (e.g., more than 6 months) between the month/year of the electronic medical record A1C compared with the self-report month/year of their most recent A1C test. Among those whose self-reported most recent A1C test was within three months of the result shown in the electronic medical record, the correlation increased to r=0.84, and self-report values were 0.47% lower than the electronic medical record value, but the median difference between A1C values was 0.0. This suggests that adults with type 1 diabetes might overestimate or underestimate their A1C, but those with the highest A1Cs tended to self-report substantially lower numbers than seen in lab reports. The survey did not ask participants where they received their most recent A1C test. Because many participants had received care at a specialty clinic at VCU Health (e.g., ophthalmology, surgery), and because their most recent visit to VCU Health was up to two years prior to taking the survey, patients with large discrepancies between dates might have received an A1C test at another medical center or physician’s office since their most recent visit at VCU Health. On the other hand, the discrepancy could also indicate inaccuracies due to memory or recall bias.

Guilfoyle and colleagues found that adolescents with type 1 diabetes self-report more frequent blood glucose self-monitoring than frequencies obtained directly from their blood glucose meter; thus, the authors suggested that a downward adjustment of self-report frequencies would be a more conservative, potentially more accurate estimate of how frequently adolescents perform blood glucose self-monitoring (Guilfoyle, Crimmins, & Hood, 2011). Because less than half of respondents in the current study (48%) had both an A1C available from both self-report and electronic medical record, and only a quarter (24%) had both values available within three months of each other, A1C values were not adjusted in the analysis for the current study to avoid generalizing findings of a subset to all participants. Future work is needed to validate these findings and further explore accuracy of self-report A1C in adults with type 1 diabetes to determine if adjusting self-report A1C is warranted.

Survey Design, Data Collection, and Response Rates

Data were collected using a five-contact, mixed-mode survey design, with strategies from the Tailored Design Method shown to maximize response rates (Dillman et al., 2014). Two modes modes—internet and mail—were used to contact participants and collect responses because email addresses were available for less than half of eligible patients. Mail and internet survey collection each have pros and cons. Mail surveys allow a token incentive to be easily enclosed and generally produce the highest survey response rates of all modes (Messer, Edwards, & Dillman, 2012). However, item non-response is highest in mail surveys as participants might overlook questions or pages, resulting in incomplete data (Messer et al., 2012). Moreover, they are expensive due to costs of printing and postage (Dillman et al., 2014). On the other hand, online surveys are advantageous for collecting data in less time and at lower costs than mail surveys. Online surveys generally have the lowest item nonresponse of all modes, so surveyors obtain the most complete data from each respondent (Messer et al., 2012). Online surveys can reach a wide range of people as 87% of adults in the United States use the internet (Pew Research Center, 2016). However, because internet use is most common among adults with younger age, higher education, higher income, and those living in suburban or urban areas rather than rural areas (Pew Research Center, 2016), response bias to web surveys often favors those of higher socioeconomic status, limiting the generalizability of the findings (Dillman et al., 2014). Moreover, it is more challenging to deliver token incentives via email, and emails from unrecognized sources can be viewed as fraudulent requests for personal information, resulting in lower response rates than mail surveys (Dillman et al., 2014).

All participants in the study were initially contacted via mail and encouraged to complete the online survey so that all participants received a monetary token incentive (to maximize response rates) and responses could be collected online (to reduce cost and item non-response). Of the 899 people contacted, 22% participated in the survey. Previous studies using the Tailored Design Method have obtained response rates ranging from 13% to 77%. Messer and Dillman (2011) sent four letters to residents in the state of Washington and requested participants to complete an online survey. Among participants who were not sent a monetary incentive, response rate was 13%; when $5 was enclosed, response rates increased to 28% to 31% (Messer & Dillman, 2011). The authors attribute low response rates to the lack of personalized correspondence, as well as potential barriers to internet access among recipients (Messer & Dillman, 2011). On the other hand, Dillman and colleagues used a five-contact, mixed-mode approach to survey doctoral students at University of Washington, achieving a response rate of 77% (Millar, 2013). In addition to strategic timing of contacts using two modes, the high response rate was likely obtained because respondents were familiar with the source, frequently used email and Internet, and felt that they could provide unique input on a relevant survey topic

(Millar, 2013; Dillman et al., 2014).

A higher response rate to the survey was expected because letters were personalized, initial letters included a monetary token incentive, and multiple contacts were sent. Moreover, participants were expected to respond to the survey because the topic was relevant to them and because they had received care at VCU Health and were thus familiar with the source. Participants in the email condition—who were contacted via mail and email—responded at a higher rate than those in the mail condition, who were sent all contacts via mail. Participants in the email condition were also more likely to complete the online survey, whereas participants in the mail condition completed more paper-and-pencil surveys. This suggests that contacting participants via multiple modes, when possible, increases survey response rates. However, for participants without an email address available, it is possible that the total response rate would have been higher if paper surveys were offered initially to these participants, whose access to and familiarity with internet could be limited.

Some participants were unreachable, which contributed to the overall response rate. Fifty-eight participants had non-deliverable addresses, due to either incorrect or outdated mailing information. Family members of seventeen participants responded that the intended letter recipient was deceased. Letters were sent to adults with type 1 diabetes who were seen at VCU Heath within the last twenty-four months so that the potential sample size of respondents would be large enough for structural equation modeling. Restricting the potential time period for participant eligibility might have reduced the number of people with outdated mailing addresses, but the potential sample size of participants would have been smaller.

Limitations

Because of the small sample size, the study might have been underpowered to detect effects of multiple predictors, and a mediator, on A1C. The sample size, despite exceeding the recommended sample of five times the number of indicators (Bentler & Chou, 1987), is relatively small sample for structural equation modeling. Structural equation model is advantageous in its ability to test large, complicated model, controlling for measurement error; however, large sample sizes are necessary to estimate these parameters (Kline, 2011). Replicating this study in a larger sample would allow better assessment of how perceived financial burden and diabetes distress, as well as demographic and socioeconomic characteristics, affect self-management behaviors and glycemic control in adults with diabetes.

Errors in diagnosis codes in electronic medical records might have contributed to the low survey response rate and thus small sample size. For example, thirty participants reported that they had type 2 diabetes, and ten participants said they had never been diagnosed with either type 1 or type 2 diabetes. Another seven participants said that although they had been diagnosed with type 1 diabetes, they had since had a kidney-pancreas transplant and as a result no longer needed to administer insulin. These coding errors limited the potential sample size, and it is unknown how many patients with type 1 diabetes were not included on the participant contact list because they were not accurately coded as having type 1 diabetes. It is also possible that some survey respondents had type 2 diabetes, which could reduce the validity of the findings.

As with all survey research, it is possible that response bias limits the generalizability of the findings. Two survey response modes were used to recruit a large, diverse sample. Respondents were diverse in demographic and socioeconomic characteristics, including age, income, race, and insurance coverage, but it is possible that survey respondents systematically differ from non-respondents. For example, non-respondents might have been unable to complete the survey due to disability or low literacy. Perceived financial burden, out-of-pocket costs for diabetes supplies, and glycemic control might be higher or lower in non-respondents than respondents. As a result, the findings might not be representative of all adults with type 1 diabetes.

The primary outcome, A1C, was measured through self-report, introducing potential inaccuracies due to memory or social desirability. Eleven percent of respondents did not report an A1C so these cases were excluded from the analysis. In addition to lowering the sample size, excluding these cases could introduce bias. Survey respondents might also differ from non-respondents, which would limit the generalizability of the findings. Finally, cross-sectional mediation often produces biased estimates, so results should be interpreted with caution.

Structural equation modeling was conducted using diagonally weighted least squares estimator, which was necessary because model constructs were measured with ordinal variables; however, this method uses listwise deletion for missing data, so the eleven percent of respondents without a self-report A1C were excluded from analysis. In addition to further reducing the sample size, listwise deletion introduces bias in cases of non-random patterns of missing data, as those with missing A1C data could systematically differ from other respondents. Household income was not included as a covariate in structural models because a high proportion of respondents had missing values for this question; thus, including income in the model would have excluded more participants from the analysis, further reducing the sample size and introducing potential bias. Instead, education was included as a covariate, which was significantly correlated with income and had low percent of missing data. However, a larger sample with more complete data is necessary for exploring how income, in addition to education, might play a role in the interplay between perceived financial burden, diabetes distress, diabetes self-management behaviors, and glycemic control.

Finally, the cross-sectional study design does not allow the interpretation of causality or mediation between predictors and health outcomes. Structural equation modeling was used to test a theoretical causal model with mediation, but cross-sectional mediation often leads to biased estimates (Maxwell & Cole, 2007), so results must be interpreted with caution. Longitudinal research, with measures collected at multiple time points, is necessary to deduce the directionality of these effects beyond correlations among constructs.

Conclusions

Two-thirds of adults with type 1 diabetes do not maintain recommended glycemic control (Miller et al., 2015), thus increasing their risk of life-threatening complications (CDC, 2014). Identifying modifiable predictors of self-management behaviors and glycemic control can inform the development of effective interventions for this population. In this sample, perceived financial burden was common and was associated with higher diabetes distress, lower quality of life, lower income, and lower perceived adequacy of health insurance. Longitudinal studies with larger sample sizes are necessary to investigate how perceived financial burden influences diabetes, self-management behaviors, glycemic control, and quality of life over time, as well as identify protective factors that may buffer against sources of burden or distress.

References

Alvarado-Martel, D., Velasco, R., Sánchez-Hernández, R. M., Carrillo, A., Nóvoa, F.J., & Wägner, A.M. (2015). Quality of life and type 1 diabetes: A study assessing patients' perceptions and self-management needs. *Patient Preference and Adherence*, 9, 1315-1323. doi: 10.2147/PPA.S87310.

American Diabetes Association. Standards of Medical Care in Diabetes—2017. *Diabetes Care*, 40:1, S1-S135.

Amsberg, S., Anderbro, T., Wredling, R., Lisspers, J., Lins, P., Adamson, U., & Johansson, U. (2009). A cognitive behavior therapy-based intervention among poorly controlled adult type 1 diabetes patients—A randomized controlled trial. *Patient Education and Counseling, 77*(1), 72-80. doi:10.1016/j.pec.2009.01.015

Anderson, R. M., Funnell, M. M., Fitzgerald, J. T., & Marrero, D. G. (2000). The Diabetes Empowerment Scale: A measure of psychosocial self-efficacy. *Diabetes Care, 23*(6), 739.

Balfe, M., Doyle, F., Smith, D., Sreenan, S., Brugha, R., Hevey, D., & Conroy, R. (2013). What's distressing about having type 1 diabetes? A qualitative study of young adults' perspectives. *BMC Endocrine Disorders, 13*:25. doi:10.1186/1472-6823-13-25

Bandura, A. (1997). *Self-efficacy: The exercise of control*. New York, NY: WH Freeman Co.

Bandura, A. (2004). Health promotion by social cognitive means. *Health Education and Behavior, 31*(2):143-64. doi: 10.1177/1090198104263660

Barnett, J.C., & Vornovitsky, M.S. (2016). *Current Population Reports, P60-257(RV), Health Insurance Coverage in the United States: 2015*, U.S. Government Printing Office, Washington, DC, 2016.

Battelino, T., Phillip, M., Bratina, N., Nimri, R., Oskarsson, P., & Bolinder, J. (2011). Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. *Diabetes Care, 34*(4), 795. doi:10.2337/dc10-1989

Bech, P., Gudex, C., & Staehr Johansen, K. (1996). The WHO (ten) Wellbeing index: Validation in diabetes. *Psychotherapy and Psychosomatics*, 65, 4, 183-90

Bentler, P.M., & Chou, C. (1987). Practical Issues in Structural Equation Modeling. Sociological Methods & Research, 16:1. DOI: 10.1177/0049124187016001004

Boomsma, A. (1985). Nonconvergence, improper solutions, and starting values in lisrel maximum likelihood estimation. *Psychometrika, 50*(2), 229-242. doi:10.1007/BF02294248

Bramlett, M. D., Blumberg, S. J., Ormson, A. E., George, J. M., Williams, K. L., Frasier, A. M., . . . Wang, F. (2014). Design and operation of the National Survey of Children with Special Health Care Needs, 2009-2010. *Vital and Health Statistics. Ser. 1, Programs and collection procedures* (57), 1.

Brown, T. (2006). *Confirmatory factor analysis for applied research.* New York: Guildford.

Burge, M., & Schade, D. (2014). Diabetes and the Affordable Care Act. *Diabetes Technology & Therapeutics, 16*(7), 399-413. doi:10.1089/dia.2014.0171

Cabana, M. D., Slish, K. K., Evans, D., Mellins, R. B., Brown, R. W., Lin, X., . . . Clark, N. M. (2006). Impact of physician asthma care education on patient outcomes. *Pediatrics, 117*(6), 2149.

Camacho, R. C., Galassetti, P., Davis, S. N., & Wasserman, D. H. (2005). Glucoregulation during and after exercise in health and insulin-dependent diabetes. *Exercise and Sport Sciences Reviews, 33*(1), 17.

Centers for Disease Control and Prevention. (2016). *Health-Related Quality of Life*. Retrieved April 1, 2017 from https://www.cdc.gov/hrqol/concept.htm

Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA: US Department of Health and Human Services; 2014.

Chiang, J. L., Kirkman, M. S., Laffel, L. M. B., & Peters, A. L. (2014). Type 1 diabetes through the life span: A position statement of the American Diabetes Association. *Diabetes Care, 37*(7), 2034. doi:10.2337/dc14-1140

Colberg, S. R., Laan, R., Dassau, E., & Kerr, D. (2015). Physical activity and type 1 diabetes. *Journal of Diabetes Science and Technology, 9*(3), 609-618. doi:10.1177/1932296814566231

Collins, S. R., Rasmussen, P. W., Beutel, S., & Doty, M. M. (2015). The problem of underinsurance and how rising deductibles will make it worse. Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2014. *Issue brief (Commonwealth Fund), 13*, 1.

Diabetes Control and Complications Trial Research Group (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *The New England Journal of Medicine, 329*(14), 977-986. doi:10.1056/NEJM199309303291401

Dillman, D. A., Smyth, J. D., & Christian, L. M. (2014). *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method (4). Somerset,* US: John Wiley & Sons, Incorporated. Retrieved from http://www.ebrary.com.proxy.library.vcu.edu

Eaddy, M. T., Cook, C. L., Day, K., Burch, S. P., & Cantrell, C. R. (2012). How patient cost-sharing trends affect adherence and outcomes: A literature review. *P&T: A Peer-Reviewed Journal for Formulary Management, 37*(1), 45.

Esbitt, S. A., Tanenbaum, M. L., & Gonzalez, J. S. (2013). Disentangling clinical depression from diabetes-specific distress: Making sense of the mess we've made. In C. E. Lloyd, F. PouIr, & N. Hermanns (Eds.), *Screening for Depression and Other Psychological Problems in Diabetes: A Practical Guide* (pp. 27-46). London: Springer London.

Fisher, L., Gonzalez, J. S., & Polonsky, W. H. (2014). The confusing tale of depression and distress in patients with diabetes: a call for greater clarity and precision. *Diabetic Medicine, 31*, 764-772. doi: 10.1111/dme.12428.

Fisher, L., Hessler, D., Glasgow, R.E., Arean, P.A., Masharani, U., Naranjo, D., & Strycker, L.A. (2013). REDEEM: A pragmatic trial to reduce diabetes distress. *Diabetes Care, 36*, 2551-8. doi: 10.2337/dc12-2493.

Fisher, L., Polonsky, W. H., Hessler, D. M., Masharani, U., Blumer, I., Peters, A. L., . . . Bowyer, V. (2015). Understanding the sources of diabetes distress in adults with type 1 diabetes. *Journal of Diabetes and Its Complications, 29*(4), 572-577. doi:10.1016/j.jdiacomp.2015.01.012

Fowler, F. J. (2009). *Applied Social Research Methods: Survey research methods (4th ed.)* Thousand Oaks, CA: SAGE Publications Ltd. doi: 10.4135/9781452230184

Galbraith, A.A., Ross-Degnan, D., Soumerai, S.B., Rosenthal, M.B., Gay, C., & Lieu, T.A. (2011). Nearly half of families in high-deductible health plans whose members have chronic conditions face substantial financial burden. *Health Affairs, 30*(2), 322-331. doi: 10.1377/hlthaff.2010.0584.

Gandhi, K., Vu, B.K., Eshtehardi, S. S., Wasserman, R. M., & Hilliard, M. E. (2015). Adherence in adolescents with type 1 diabetes: Strategies and considerations for assessment in research and practice. *Diabetes Management, 5*(6), 485-498. doi:10.2217/dmt.15.41

Guilfoyle, S.M., Crimmins, N.A., & Hood, K.K. (2011). Blood glucose monitoring and glycemic control in adolescents with type 1 diabetes: meter downloads versus self-report. *Pediatric Diabetes*, 12, 560–566. doi: 10.1111/j.1399-5448.2010.00735.x

Hajos, T. R. S., Pouwer, F., Skovlund, S. E., Den Oudsten, B. L., Geelhoed-Duijvestijn, P. H., Tack, C. J., & Snoek, F. J. (2013). Psychometric and screening properties of the WHO-5 Well-being index in adult outpatients with type 1 or type 2 diabetes mellitus. *Diabetic Medicine, 30*(2), e63-e69. doi:10.1111/dme.12040

Harris, P.A., Taylor, R., Thielke, R., Payne, J, Gonzalez, N., & Conde, J.G. (2009). Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics, 42(2),* 377-81. doi: 10.1016/j.jbi.2008.08.010

Hermanns, N., Kulzer, B., Ehrmann, D., Bergis-Jurgan, N., & Haak, T. (2013). The effect of a diabetes education programme (PRIMAS) for people with type 1 diabetes: Results of a randomized trial. *Diabetes Research and Clinical Practice, 102*(3), 149-57. doi: 10.1016/j.diabres.2013.10.009.

Hilliard, M.E., Mann, K.A., Peugh, J.L., & Hood, K.K. (2013). How poorer quality of life in adolescence predicts subsequent type 1 diabetes management and control. *Patient Education and Counseling, 91*(1):120-5. doi: 10.1016/j.pec.2012.10.014.

Hilliard, M.E., Harris, M.A., & Weissberg-Benchell, J. (2012). Diabetes resilience: A model of risk and protection in type 1 diabetes. *Current Diabetes Reports, 12*(6), 739-748. doi:10.1007/s11892-012-0314-3

Hilliard, M.E., Yi-Frazier, J.P., Hessler, D., Butler, A.M., Anderson, B.J., & Jaser, S. (2016). Stress and A1c among people with diabetes across the lifespan. *Current Diabetes Reports, 16*(8), 1-10. doi:10.1007/s11892-016-0761-3

Hua, X., Carvalho, N., Tew, M., Huang, E. S., Herman, W. H., & Clarke, P. (2016). Expenditures and prices of antihyperglycemic medications in the United States: 2002-2013. *JAMA, 315*(13), 1400. doi:10.1001/jama.2016.0126

Jacobson, A. M., Braffett, B. H., Cleary, P. A., Gubitosi-Klug, R. A., & Larkin, M. E. (2013). The long-term effects of type 1 diabetes treatment and complications on health-related quality of life: A 23-year follow-up of the Diabetes Control and Complications/Epidemiology of Diabetes Interventions and Complications cohort. *Diabetes Care, 36*(10), 3131. doi:10.2337/dc12-2109

James, M. L., Green, L., Amiel, S. A., & Choudhary, P. (2016). Evaluation of the effect of carbohydrate intake on postprandial glucose in patients with type 1 diabetes treated with insulin pumps. *Journal of Diabetes Science and Technology, 10*(6), 1287-1293. doi:10.1177/1932296816646797

Jaser, S., Patel, N., Xu, M., Tamborlane, W., & Grey, M. (2017). Stress and coping predicts adjustment and glycemic control in adolescents with type 1 diabetes. *Annals of Behavioral Medicine, 51*(1), 30-38. doi:10.1007/s12160-016-9825-5

Jeon, Y. H., Essue, B., Jan, S., Ills, R., & Whitworth, J. A. (2009). Economic hardship associated with managing chronic illness: A qualitative inquiry. *BMC Health Services Research, 9*, 182-182. doi:10.1186/1472-6963-9-182

Joensen, L. E., Almdal, T. P., & Willaing, I. (2016). Associations between patient characteristics, social relations, diabetes management, quality of life, glycaemic control and emotional burden in type 1 diabetes. *Primary Care Diabetes, 10*(1), 41-50. doi:10.1016/j.pcd.2015.06.007

Johnston-Brooks, C. H., Lewis, M. A., & Garg, S. (2002). Self-efficacy impacts self-care and HbA1c in young adults with type I diabetes. *Psychosomatic medicine, 64*(1), 43.

Jones, A., Vallis, M., & PouIr, F. (2015). If it does not significantly change HbA1c levels why should I waste time on it? A plea for the prioritization of psychological well-being in people with diabetes. *Diabetic Medicine, 32*(2), 155-163. doi: 10.1111/dme.12620.

Lašaitė, L., Ostrauskas, R., Žalinkevičius, R., Jurgevičienė, N., & Radzevičienė, L. (2016). Diabetes distress in adult type 1 diabetes mellitus men and women with disease onset in childhood and in adulthood. *Journal of Diabetes and Its Complications, 30*(1), 133-137. doi:10.1016/j.jdiacomp.2015.09.012

Lin, M. H., Connor, C. G., Ruedy, K. J., Beck, R. W., Kollman, C., Buckingham, B., . . . Wood, J. R. (2013). Race, socioeconomic status, and treatment center are associated with insulin pump therapy in youth in the first year following diagnosis of type 1 diabetes. *Diabetes Technology & Therapeutics, 15*(11), 929. doi:10.1089/dia.2013.0132

Li, C. H. (2016). Confirmatory factor analysis with ordinal data: Comparing robust maximum likelihood and diagonally weighted least squares. Behavior Research Methods, 48(3):936-49. doi: 10.3758/s13428-015-0619-7.

Livingstone, S. J., Levin, D., Looker, H. C., Lindsay, R. S., Wild, S. H., Joss, N., . . . Colhoun, H. M. (2015). Estimated life expectancy in a Scottish cohort with type 1 diabetes, 2008-2010. *JAMA, 313*(1), 37. doi:10.1001/jama.2014.16425

Lloyd, C. E., Pambianco, G., & Orchard, T. J. (2010). Does diabetes-related distress explain the presence of depressive symptoms and/or poor self-care in individuals with type 1 diabetes? *Diabetic Medicine, 27*(2), 234-237. doi:10.1111/j.1464-5491.2009.02896.xLloyd, C., Smith, J., & Weinger, K. (2005). Stress and diabetes: a review of the links. *Diabetes Spectrum*, *18*(2), 121-127.

Marsh, H.W., Wen, Z., Hau, K., Little, T.D., Bovaird, J.A., & Widaman, K.F. (2007). Unconstrained Structural Equation Models of Latent Interactions: Contrasting Residual- and Mean-Centered Approaches. *Structural Equation Modeling: A Multidisciplinary Journal, 14(4)*, 570-580. doi:/10.1080/10705510701303921

Maxwell, S. E., & Cole, D. A. (2007). Bias in cross-sectional analyses of longitudinal mediation. *Psychological Methods, 12*(1), 23-44. doi:10.1037/1082-989X.12.1.23

Messer, B. L., & Dillman, D. A. (2011). Surveying the general public over the internet using address-based sampling and mail contact procedures. *Public Opinion Quarterly, 75*(3), 429-457. doi:10.1093/poq/nfr021

Messer, B.L., Edwards, M.L., & Dillman, D.A. (2012). Determinants of item nonresponse to Web and mail respondents in three address-based mixed-mode surveys of the general public. Technical Report 12-001. Retrieved April 1, 2017 from https://www.sesrc.wsu.edu/dillman/papersIb/2012.html

Millar, M. M., & Dillman, D. A. (2011). Improving response to Web and mixed-mode surveys. *Public Opinion Quarterly, 75*(2), 249-269. doi:10.1093/poq/nfr003

Miller, K. M., Beck, R. W., Bergenstal, R. M., Goland, R. S., Haller, M. J., McGill, J. B., . . . Hirsch, I. B. (2013). Evidence of a strong association between frequency of self-monitoring of blood glucose and hemoglobin A1c levels in T1D exchange clinic registry participants. *Diabetes Care, 36*(7), 2009. doi:10.2337/dc12-1770

Miller, K. M., Foster, N. C., Beck, R. W., Bergenstal, R. M., Dubose, S. N., Dimeglio, L. A., . . .

Tamborlane, W. V. (2015). Current state of type 1 diabetes treatment in the U.S.: Updated data from the T1D Exchange clinic registry. *Diabetes Care, 38*(6), 971. doi:10.2337/dc15-0078

Mohn, J., Graue, M., Assmus, J., Zoffmann, V., B. Thordarson, H., Peyrot, M., & Rokne, B. (2015). Self-reported diabetes self-management competence and support from healthcare providers in achieving autonomy are negatively associated with diabetes distress in adults with type 1 diabetes. *Diabetic Medicine, 32*(11), 1513-1519. doi:10.1111/dme.12818

Naranjo, D., Mulvaney, S., McGrath, M., Garnero, T., & Hood, K. (2014). Predictors of self-management in pediatric type 1 diabetes: Individual, family, systemic, and technologic influences. *Current Diabetes Reports, 14*(11), 1-8. doi:10.1007/s11892-014-0544-7

Nicolucci, A., Kovacs Burns, K., Holt, R. I. G., Comaschi, M., Hermanns, N., Ishii, H., . . . Peyrot, M. (2013). Diabetes Attitudes, Wishes and Needs second study (DAWN2™): Cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabetic Medicine, 30*(7), 767-777. doi:10.1111/dme.12245

Nijboer, C., Triemstra, M., Tempelaar, R., Sanderman, R., & van Den Bos, G. A. M. (1999). Measuring both negative and positive reactions to giving care to cancer patients: Psychometric qualities of the Caregiver Reaction Assessment (CRA). *Social Science & Medicine, 48*(9), 1259-1269. doi:10.1016/S0277-9536(98)00426-2

Noser, A. E., Huffhines, L., Clements, M. A., & Patton, S. R. (2016). Diabetes conflict outstrips the positive impact of self-efficacy on youth adherence and glycemic control in type 1 diabetes. *Pediatric Diabetes*. doi:10.1111/pedi.12471

Paez, K. A., Zhao, L., & Hwang, W. (2009). Rising out-of-pocket spending for chronic conditions: A ten-year trend. *Health Affairs (Project Hope), 28*(1), 15.

doi:10.1377/hlthaff.28.1.15

Pallayova, M., & Taheri, S. (2014). Targeting diabetes distress: The missing piece of the successful type 1 diabetes management puzzle. *Diabetes Spectrum: A Publication of the American Diabetes Association, 27*(2), 143. doi:10.2337/diaspect.27.2.143

Parkin, C. G., & Davidson, J. A. (2009). Value of self-monitoring blood glucose pattern analysis in improving diabetes outcomes. *Journal of Diabetes Science and Technology, 3*(3), 500. DOI: 10.1177/193229680900300314

Patel, M. R., Caldwell, C. H., Song, P. X., & Wheeler, J. R. (2014). Patient perceptions of asthma-related financial burden: Public vs private health insurance in the United States. *Annals of Allergy, Asthma & Immunology, 113*(4), 398-403. doi:10.1016/j.anai.2014.07.004

Pew Research Center. (2016, Sept. 7). *13% of Americans don't use the internet. Who are they?* Retrieved April 1, 2017 from http://www.pewresearch.org/fact-tank/2016/09/07/some-americans-dont-use-the-internet-who-are-they/

Piette, J. D., Beard, A., Rosland, A. M., & McHorney, C. A. (2011). Beliefs that influence cost-related medication non-adherence among the "haves" and "have nots" with chronic diseases. *Patient Preference and Adherence, 5*, 389-396. doi:10.2147/PPA.S23111

Powers, M. A., Richter, S. A., Ackard, D. M., & Craft, C. (2017). Diabetes distress among persons with type 1 diabetes. *The Diabetes Educator, 43*(1), 105-113. doi:10.1177/0145721716680888

Riddell, M., & Perkins, B. A. (2009). Exercise and glucose metabolism in persons with diabetes mellitus: perspectives on the role for continuous glucose monitoring. *Journal of Diabetes Science and Technology, 3*(4), 914. DOI: 10.1177/193229680900300439

Rosseel, Y. (2012). lavaan: An R Package for Structural Equation Modeling. *Journal of Statistical Software*, 48(2), 1-36. DOI: 10.3389/fpsyg.2014.01521

Sacco, W. P., & Bykowski, C. A. (2010). Depression and hemoglobin A1c in type 1 and type 2 diabetes: The role of self-efficacy. *Diabetes Research and Clinical Practice, 90*(2), 141-146. doi:10.1016/j.diabres.2010.06.026

Sacks, D. B., Arnold, M., Bakris, G. L., Bruns, D. E., Horvath, A. R., Kirkman, M. S., . . . Nathan, D. M. (2011). Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Diabetes Care, 34*(6), e61. doi:10.2337/dc11-9998

Schmitt, A., Gahr, A., Hermanns, N., Kulzer, B., Huber, J., & Haak, T. (2013). The Diabetes Self-Management Questionnaire (DSMQ): Development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. *Health and Quality of Life Outcomes, 11*, 138. doi:10.1186/1477-7525-11-138

Schmitt, A., Reimer, A., Hermanns, N., Huber, J., Ehrmann, D., Schall, S., & Kulzer, B. (2016). Assessing diabetes self-management with the Diabetes Self-Management Questionnaire (DSMQ) can help analyse behavioural problems related to reduced glycaemic control. *PloS One, 11*(3), e0150774. doi:10.1371/journal.pone.0150774

Schofield, L. S. (2015). Correcting for measurement error in latent variables used as predictors. *The Annals of Applied Statistics, 9*(4), 2133-2152. doi:10.1214/15-AOAS877

Schwarzer, R., Schuz, B., Ziegelmann, J. P., Lippke, S., Luszczynska, A., & Scholz, U. (2007). Adoption and maintenance of four health behaviors: Theory-guided longitudinal studies on dental flossing, seat belt use, dietary behavior, and physical activity. *Annals of Behavioral Medicine: a publication of the Society of Behavioral Medicine, 33*(2), 156.

DOI: 10.1080/08836610701308221

Strandberg, R. B., Graue, M., Wentzel-Larsen, T., Peyrot, M., & Rokne, B. (2014). Relationships of diabetes-specific emotional distress, depression, anxiety, and overall well-being with HbA1c in adult persons with type 1 diabetes. *Journal of Psychosomatic Research, 77*(3), 174-179. doi:10.1016/j.jpsychores.2014.06.015

Stupiansky, N. W., Hanna, K. M., Slaven, J. E., Weaver, M. T., & Fortenberry, J. D. (2013). Impulse control, diabetes-specific self-efficacy, and diabetes management among emerging adults with type 1 diabetes. *Journal of Pediatric Psychology, 38*(3), 247-254. doi:10.1093/jpepsy/jss110

Sturt, J., Dennick, K., Due-Christensen, M., & McCarthy, K. (2015). The detection and management of diabetes distress in people with type 1 diabetes. *Current Diabetes Reports, 15*(11), 1-14. doi:10.1007/s11892-015-0660-z

Sultan, S., Epel, E., Sachon, C., Vaillant, G., & Hartemann-Heurtier, A. (2008). A longitudinal study of coping, anxiety and glycemic control in adults with type 1 diabetes. *Psychology & Health, 23*(1), 73-89. doi:10.1080/14768320701205218

Tanenbaum, M. L., & Gonzalez, J. S. (2012). The influence of diabetes on a clinician-rated assessment of depression in adults with type 1 diabetes. *The Diabetes Educator, 38*(5), 695-704. doi:10.1177/0145721712452795

Tao, B., Pietropaolo, M., Atkinson, M., Schatz, D., & Taylor, D. (2010). Estimating the cost of type 1 diabetes in the U.S.: A propensity score matching method (a matching method). *PLoS ONE, 5*(7), e11501. doi:10.1371/journal.pone.0011501

Topp, C. W., Østergaard, S. D., Søndergaard, S., & Bech, P. (2015). The WHO-5 Well-Being Index: A systematic review of the literature. *Psychotherapy and Psychosomatics, 84*(3),

167. doi:10.1159/000376585

Tovote, K. A., Fleer, J., Snippe, E., Peeters, A. C. T. M., Emmelkamp, P. M. G., Sanderman, R., . . . Schroevers, M. J. (2014). Individual mindfulness-based cognitive therapy and cognitive behavior therapy for treating depressive symptoms in patients with diabetes: Results of a randomized controlled trial. *Diabetes Care, 37*(9), 2427. doi:10.2337/dc13-2918

Tran, V. T., Barnes, C., Montori, V. M., Falissard, B., & Ravaud, P. (2015). Taxonomy of the burden of treatment: a multi-country web-based qualitative study of patients with chronic conditions. *BMC Medicine, 13*, 115. doi:10.1186/s12916-015-0356-x

Tregea, H., Lee, C., Browne, J. L., Pouwer, F., & Speight, J. (2016). Does self-efficacy mediate the cross-sectional relationship between perceived quality of health care and self-management of diabetes? Results from Diabetes MILES - Australia. *Psychology & Health*, 1-25. doi:10.1080/08870446.2015.1128543

Tuomilehto, J., Borch-Johnsen, K., Molarius, A., Forsén, T., Rastenyte, D., Sarti, C., & Reunanen, A. (1998). Incidence of cardiovascular disease in type 1 (insulin-dependent) diabetic subjects with and without diabetic nephropathy in Finland. *Diabetologia, 41*(7), 784-790. doi:10.1007/s001250050988

Van Der Ven, N. C., Weinger, K., Yi, J., Pouwer, F., Adèr, H., Van Der Ploeg, H. M., & Snoek, F. J. (2003). The Confidence in Diabetes Self Care scale: Psychometric properties of a new measure of diabetes-specific self-efficacy in Dutch and US patients with type 1 diabetes. *Diabetes Care, 26*(3), 713.

van Dijk, J.W., Eijsvogels, T. M., Nyakayiru, J., Schreuder, T. H. A., Hopman, M. T., Thijssen, D. H., & van Loon, L. J. C. (2016). Glycemic control during consecutive days with prolonged walking exercise in individuals with type 1 diabetes mellitus. *Diabetes Research and Clinical Practice, 117*, 74-81. doi:10.1016/j.diabres.2016.04.053

van Son, J., Nyklícek, I., Pop, V. J., Blonk, M. C., Erdtsieck, R. J., Spooren, P. F., . . . Pouwer, F. (2013). The effects of a mindfulness-based intervention on emotional distress, quality of life, and HbA(1c) in outpatients with diabetes (DiaMind): A randomized controlled trial. *Diabetes Care, 36*(4), 823. doi:10.2337/dc12-1477

Wallston, K., Rothman, R., & Cherrington, A. (2007). Psychometric properties of the Perceived Diabetes Self- Management Scale (PDSMS). *Journal of Behavioral Medicine, 30*(5), 395-401. doi:10.1007/s10865-007-9110-y

Weinstock, S. R., Xing, M. D., Maahs, R. D., Michels, L. A., Rickels, M. M., Peters, N. A., . . . Beck, W. R. (2013). Severe hypoglycemia and diabetic ketoacidosis in adults with type 1 diabetes: Results from the T1D Exchange clinic registry. *The Journal of Clinical Endocrinology & Metabolism, 98*(8), 3411-3419. doi:10.1210/jc.2013-1589

Wiley, J., Westbrook, M., Long, J., Greenfield, J. R., Day, R. O., & Braithwaite, J. (2015). Multidisciplinary diabetes team care: The experiences of young adults with Type 1 diabetes. *Health Expectations, 18*(5), 1783-1796. doi:10.1111/hex.12170

Willi, S. M., Miller, K. M., Dimeglio, L. A., Klingensmith, G. J., Simmons, J. H., Tamborlane, W. V., . . . Lipman, T. H. (2015). Racial-ethnic disparities in management and outcomes among children with type 1 diabetes. *Pediatrics, 135*(3), 424. doi:10.1542/peds.2014-1774

Williams, G. C., McGregor, H. A., King, D., Nelson, C. C., & Glasgow, R. E. (2005). Variation in perceived competence, glycemic control, and patient satisfaction: Relationship to autonomy support from physicians. *Patient Education and Counseling, 57*(1), 39-45.

doi:10.1016/j.pec.2004.04.001

Wong, J. C., Foster, N. C., Maahs, D. M., Raghinaru, D., Bergenstal, R. M., Ahmann, A. J., . . . Adi, S. (2014). Real-time continuous glucose monitoring among participants in the T1D Exchange clinic registry. *Diabetes Care, 37*(10), 2702. doi:10.2337/dc14-0303

World Health Organization. (1949). *WHO Constitution*. Retrieved April 1, 2017 from http://www.who.int/about/en/

Zoffmann, V., Vistisen, D., & Due-Christensen, M. (2014). A cross-sectional study of glycaemic control, complications and psychosocial functioning among 18 to 35 year-old adults with type 1 diabetes. *Diabetic Medicine, 31*(4), 493-499. doi:10.1111/dme.12363

Tables and Figures

Table 1

Timeline of Contacts for Participants in Email and Mail Conditions

Email Condition		Mail Condition	
Day	Contact	Day	Contact
1	Letter with $1 bill	1	Letter with $1 bill
7	Email reminder	7	Postcard
12	Email reminder	21	Reminder letter
22	Mail survey packet	39	Mail survey packet
41	Final reminder email	54	Final reminder letter

Table 2

Demographic Characteristics of the Sample

Characteristic	*M* or *n*	*SD* or %
Age, *years* (*n*=235)	44.7	10.8
Household size, *number of people* (*n*=232)	2.7	1.5
Body Mass Index, kg/m^2 (*n*=231)	27.5	6.2
Gender (*n*=233)		
Female	135	57.4%
Male	98	41.7%
Race/Ethnicity (*n*=233)		
White or Caucasian (non-Hispanic)	147	62.6%
Black or African American (non-Hispanic)	73	31.1%
Other	13	5.5%
Household Income (*n*=232)		
Less than $25,000	80	34.0%
$25,000-34,999	23	9.8%
$35,000-49,999	15	6.4%
$50,000-74,999	35	14.9%
$75,000-99,999	18	7.7%
$100,000 or more	33	14.0%
Prefer not to answer	28	12.1%
Education (*n*=235)		
Did not complete high school	12	5.1%
High school diploma or GED	48	20.4%
Some college but no degree	53	22.6%
Associates degree	24	10.2%
Bachelor's degree	63	26.8%
Master's, doctorate, or professional degree	35	14.9%
Marital Status (*n*=233)		
Single	69	29.4%
Married or cohabitating	116	49.4%
Divorced or separated	44	18.7%
Widowed	4	1.7%
Health Insurance Coverage (*n*=234)		
Private insurance	109	46.4%
Medicare, Medicaid, or Military	70	29.8%
Uninsured	55	23.4%
Employment Status (*n*=233)		
Not working	111	47.2%
Working part-time	27	11.5%
Working full-time	95	40.4%

Table 3

Diabetes and Health Characteristics of the Sample

Characteristic	*M* or *n*	*SD* or %
Self-report A1C result, % (*n*=209)	8.0	1.7
Age at diagnosis, years (*n*=225)	20.6	13.0
Diabetes duration, years (*n*=225)	23.8	13.1
Total chronic comorbidities/complications (*n*=235)	2.1	1.9
Insulin regimen (*n*=229)		
Insulin pump	84	35.7%
Multiple daily injections	145	61.7%
Continuous glucose monitor use (*n*=231)		
Yes	111	47.2%
No	120	51.1%
Chronic complications/comorbidities		
Depression	101	43.0%
Neuropathy	89	37.9%
Retinopathy	82	34.9%
Sleeping problems	81	34.5%
Sexual dysfunction	50	21.3%
Nephropathy	47	20.0%
Heart disease	33	14.0%
Foot ulcers	21	8.9%
Ever experienced severe hypoglycemia (*n*=234)		
Yes	119	50.6%
No	115	48.9%
Ever experienced diabetic ketoacidosis (*n*=230)		
Yes	88	37.4%
No	142	60.4%

Table 4

Correlations among Constructs and Demographic Characteristics

Measure	1	2	3	4	5	6	7	8	9	10	11
1. A1C	–										
2. Self-Management Behaviors	-.35**	–									
3. Diabetes Distress	.27**	-.48**	–								
4. Perceived Financial Burden	.19**	-.23**	.28**	–							
5. Diabetes Self-Efficacy	-.30**	.37**	-.41**	-.23**	–						
6. Income	-.34**	.09	-.07	-.27**	.16*	–					
7. Education	-.24**	.08	.01	-.14*	.12	.59**	–				
8. Chronic complications	.24**	-.16*	.31**	.19**	-.20**	-.43**	-.42**	–			
9. BMI	.09	-.24**	.22**	.01	-.06	.03	-.03	.07	–		
10. Duration	-.06	.05	-.06	-.04	.10	.13	.03	.18**	.04	–	
11. Age	-.04	.11	-.23**	-.08	.03	-.03	-.17**	.14*	-.04	.42**	–

*$p<0.05$, **$p<0.01$

Table 5

Demographic Group Differences in A1C

Characteristic	*n*	A1C *M*	*SD*	One-way ANOVA *F*	*df*	*p-value*
Race/Ethnicity						
White/Caucasian (Non-Hispanic)	136	7.80	1.60	4.92	2,204	0.008
Black/African American (Non-Hispanic)	58	8.29	1.81			
Other	13	9.17	1.79			
Health Insurance						
Uninsured	44	8.95	1.81	9.50	2, 205	<0.001
Public	57	8.00	1.82			
Private	107	7.66	1.50			
Marital Status						
Single	55	8.33	1.72	6.53	2, 205	0.002
Married or Cohabit	112	7.65	1.70			
Divorced/Separated or Widowed	41	8.65	1.58			
Treatment Method						
Multiple daily injections	122	8.43	1.83	14.36	1, 202	<0.001
Insulin pump	82	7.53	1.38			
Employment						
Not employed	92	8.09	1.70	0.17	1, 206	0.677
Employed	116	7.99	1.75			
Gender						
Male	88	7.90	1.47	0.98	1, 205	0.324
Female	119	8.14	1.90			

Table 6

Mean, Standard Deviation (SD), and Reliability of Scales and Subscales

Scale or Sub-Scale	Number of items	Cronbach's alpha	Mean	Standard Deviation
Type 1 Diabetes Distress Scale	28	0.92	2.07	0.80
Powerlessness distress	5	0.83	2.86	1.26
Management distress	4	0.77	1.95	1.01
Hypoglycemia distress	4	0.82	2.20	1.25
Negative social perceptions	4	0.78	1.82	1.09
Eating distress	3	0.76	2.25	1.15
Physician distress	4	0.81	1.59	0.97
Family/friend distress	4	0.84	1.85	1.06
Diabetes Self-Management Questionnaire	16	0.82	3.27	0.41
Blood glucose monitoring	3	0.76	3.20	0.80
Insulin/medication management	2	0.55	3.75	0.44
Physical activity	3	0.72	3.26	0.65
Diet	4	0.73	2.83	0.61
Healthcare use	3	0.48	3.58	0.55
Diabetes Empowerment Scale-Short Form	8	0.84	3.72	0.82
Perceived Financial Burden	5	0.87	2.94	1.20

Table 7

Factor Loadings and Covariance Terms of the Revised Measurement Model

	B	*S.E.*	*p-value*	*β*
Factor Loadings				
Self-management behaviors (SMB)				
Physical activity	1	–	–	0.56
Diet	1.14	0.19	<0.001	0.68
Blood glucose monitoring	1.52	0.27	<0.001	0.70
Insulin/medication management	0.62	0.13	<0.001	0.51
Diabetes distress (DD)				
Powerlessness	1	–	–	0.72
Management distress	0.97	0.13	<0.001	0.86
Hypoglycemia	0.63	0.11	<0.001	0.45
Negative social perceptions	0.56	0.10	<0.001	0.46
Eating distress	1.05	0.14	<0.001	0.82
Physician distress	0.68	0.10	<0.001	0.62
Perceived financial burden (PFB)				
PFB item 1	1	–	–	0.83
PFB item 3	1.08	0.04	<0.001	0.90
PFB item 4	1.05	0.04	<0.001	0.87
PFB item 5	1.03	0.04	<0.001	0.86
PFB item 6	0.89	0.05	<0.001	0.74
Diabetes self-efficacy (DSE)				
DSE item 2	1	–	–	0.79
DSE item 3	0.93	0.05	<0.001	0.73
DSE item 4	0.92	0.05	<0.001	0.73
DSE item 5	0.95	0.05	<0.001	0.75
DSE item 6	0.97	0.05	<0.001	0.77
DSE item 7	1.04	0.05	<0.001	0.82
DSE item 8	1.03	0.05	<0.001	0.82
Covariance				
SMB ~~ DD	-0.22	0.05	<0.001	-0.66
SMB ~~ PFB	-0.06	0.03	0.032	-0.19
SMB ~~ DSE	0.15	0.03	<0.001	0.52
DD ~~ PFB	0.25	0.06	<0.001	0.33
DD ~~ DSE	-0.38	0.07	<0.001	-0.53
PFB ~~ DSE	-0.16	0.04	<0.001	-0.24

Note: Number of observations used=223; χ^2=412.2, df=203, p<0.001; CFI=0.93, TLI=0.92, RMSEA=0.07, SRMR=0.07

Table 8

Factor Loadings and Regression Coefficients of Structural Model 1

	B	*S.E.*	*p-value*	*β*
Factor Loadings				
Self-management behaviors (SMB)				
Exercise	1	—	—	0.59
Diet	1.07	0.15	<0.001	0.67
Blood glucose monitoring	1.34	0.23	<0.001	0.63
Insulin/medication management	0.72	0.13	<0.001	0.62
Diabetes distress (DD)				
Powerlessness	1	—	—	0.68
Management distress	1.03	0.14	<0.001	0.82
Hypoglycemia distress	0.63	0.11	<0.001	0.41
Negative social perceptions	0.54	0.09	<0.001	0.42
Eating distress	1.21	0.15	<0.001	0.88
Physician distress	0.71	0.10	<0.001	0.63
Perceived financial burden (PFB)				
PFB item 1	1	—	—	0.87
PFB item 3	1.05	0.04	<0.001	0.91
PFB item 4	1.00	0.03	<0.001	0.87
PFB item 5	0.96	0.04	<0.001	0.84
PFB item 6	0.88	0.05	<0.001	0.77
Regressions				
A1C				
Self-management behaviors (b)	-0.99	0.50	0.05	-0.22
Perceived financial burden (c1)	0.13	0.15	0.38	0.07
Diabetes distress (c2)	0.35	0.24	0.14	0.17
Education	-0.22	0.09	0.02	-0.20
Race (White vs. non-White)	0.46	0.27	0.08	0.13
Age	-0.01	0.01	0.38	-0.06
Self-management behaviors				
Perceived financial burden (a1)	0.01	0.03	0.74	0.02
Diabetes distress (a2)	-0.34	0.06	<0.001	-0.74
Covariance				
DD ~~ PFB	0.24	0.06	<0.001	0.34
Indirect effects$^+$	*B*	Lower CI	Upper CI	
Indirect effect (PFB)	-0.01	-0.11	0.06	
Indirect effect (DD)	0.34	-0.09	0.87	
Total effect (PFB)	0.12	-0.17	0.40	
Total effect (DD)	0.69	0.40	0.06	

Note: Number of observations used=202; χ^2=321.8, df=144, p<0.001; CFI=0.92, TLI=0.90, RMSEA=0.08, SRMR=0.08.

$^+$Confidence Intervals for the indirect effects are percentile bootstrap intervals.

Table 9

Factor Loadings and Regression Coefficients of Structural Model 2

	B	*SE*	*p-value*	*β*
Factor Loadings				
Self-management behaviors (SMB)				
Exercise	1	—	—	0.58
Diet	1.01	0.145	<0.001	0.63
Blood glucose monitoring	1.40	0.227	<0.001	0.66
Insulin/medication management	0.75	0.133	<0.001	0.63
Diabetes distress (DD)				
Powerlessness	1	—	—	0.68
Management distress	1.11	0.14	<0.001	0.89
Hypoglycemia distress	0.65	0.10	<0.001	0.43
Negative social perceptions	0.47	0.09	<0.001	0.37
Eating distress	1.18	0.14	<0.001	0.86
Physician distress	0.68	0.09	<0.001	0.60
Perceived financial burden (PFB)				
PFB item 1	1	—	—	0.87
PFB item 3	1.05	0.04	<0.001	0.91
PFB item 4	1.00	0.03	<0.001	0.87
PFB item 5	0.96	0.04	<0.001	0.83
PFB item 6	0.88	0.05	<0.001	0.76
Diabetes self-efficacy (DSE) * DD				
DSE item 4* Powerlessness	1	—	—	0.56
DSE item 5* Management distress	1.18	0.15	<0.001	0.77
DSE item 6* Hypoglycemia distress	0.91	0.13	<0.001	0.50
Diabetes self-efficacy (DSE) * PFB				
DSE item 4* PFB item 1	1	—	—	0.60
DSE item 5* PFB item 3	1.15	0.13	<0.001	0.63
DSE item 6* PFB item 4	1.18	0.21	<0.001	0.65
Regressions				
A1C				
Self-management behaviors (b)	-1.09	0.55	0.05	-0.24
Perceived financial burden (c1)	0.13	0.15	0.39	0.07
Diabetes distress (c2)	0.33	0.24	0.18	0.16
Education	-0.22	0.09	0.02	-0.20
Race (White vs. Non-White)	0.44	0.27	0.10	0.12
Age	-0.01	0.01	0.35	-0.07
Self-management behaviors				
Perceived financial burden (a1)	0.01	0.03	0.78	0.02

Diabetes distress (a2)	-0.33	0.06	<0.001	-0.72
DES x DD	0.01	0.04	0.69	0.04
DES x PFB	0.04	0.04	0.37	0.10
Covariance				
DD ~~ PFB	0.24	0.05	<0.001	0.34
DD ~~ DSE*DD	-0.35	0.08	<0.001	-0.42
DD ~~ DSE*PFB	-0.10	0.07	0.16	-0.12
PFB ~~ DSE*DD	-0.12	0.06	0.04	-0.14
PFB ~~ DSE*PFB	0.02	0.06	0.81	0.02
DSE*DD ~~ DSE*PFB	0.59	0.11	<0.001	0.57
Indirect Effects[+]	*B*	Lower CI	Upper CI	
Indirect effect (PFB)	-0.01	-0.37	0.11	
Indirect effect (DD)	0.36	-0.21	3.24	
Total effect (PFB)	0.12	-0.17	0.41	
Total effect (DD)	0.69	0.30	1.09	

Note: Number of observations used=200; χ^2=478.4, df=260, p<0.001; CFI= 0.91, TLI= 0.89, RMSEA= 0.06, SRMR=0.07

[+] Confidence Intervals for the indirect effects are percentile bootstrap intervals.

Table 10

Correlates of Perceived Financial Burden

	1	2	3	4	5	6	7	8	9	10	11
1. PFB	1										
2. A1C	.19**	1									
3. Education	-.14*	-.24**	1								
4. Household size	.06	-.01	-.08	1							
5. Income	-.27**	-.34**	.59**	-.02	1						
6. General QOL	-.16*	-.10	.13*	-.05	.15*	1					
7. Complications	.19**	.24**	-.42**	.08	-.43**	-.24**	1				
Insurance adequacy:											
8. Benefits	-.40**	-.09	.04	-.02	.19*	.13	-.06	1			
9. Costs	-.37**	-.19*	-.01	-.03	.11	.13	-.13	.49**	1		
10. Providers	-.42**	-.06	.03	-.06	.18*	.20**	-.15*	.40**	.36**	1	
11. Desire to keep^{+}	-.36**	-.08	-.04	-.10	.11	.19*	-.03	.39**	.44**	.48**	1

*p<.05, **p<.01, $^{+}$Item is reverse-coded

Note: Variables 8-11 include only participants with health insurance. PFB=Perceived financial burden, QOL=quality of life

Table 11

Demographic Group Differences in Perceived Financial Burden

Characteristic	*n*	Perceived Financial Burden *M*	 *SD*	One-way ANOVAs of group differences in Perceived Financial Burden *F*	 *df*	 *p-value*
Health Insurance						
Uninsured	55	3.41	1.29	5.66	2, 231	<0.01
Public	70	2.84	1.22			
Private	109	2.77	1.09			
Marital Status						
Single	69	2.98	1.22	0.51	2, 230	0.60
Married or cohabitating	116	2.86	1.19			
Divorced/separated or widowed	48	3.06	1.24			
Race/Ethnicity						
Non-Hispanic White	147	2.99	1.21	0.48	2, 230	0.62
Non-Hispanic Black	73	2.82	1.18			
Other	13	2.92	1.28			
Employment status						
Not working	111	3.02	1.26	1.20	1, 231	0.27
Working	122	2.85	1.14			

Table 12

Out-of-Pocket Costs for Diabetes Supplies in the Previous Twelve Months

	n(%) who incurred out-of-pocket cost		Reported out-of-pocket expenses incurred			
Type of supplies	*n*	%	*M*	*SD*	Median	*n*
Insulin	156	66.4	766.24	1,178.61	340.00	141
Testing strips	155	66.0	621.63	1,318.84	202.00	142
Needles or syringes	104	44.3	318.34	582.43	90.00	92
Insulin pump supplies	57	24.3	1,248.73	1,592.41	750.00	49
Continuous glucose monitor supplies	44	18.7	1,407.13	2,230.35	672.50	38
Glucagon	29	12.3	104.93	166.03	40.00	24

Table 13

Financial Variables Associated with Perceived Financial Burden

			PFB		Independent samples t-tests			
		n	*M*	*SD*	*t*	*df*	*p*	*SE*
Discussed costs with provider	No	151	2.67	1.10	-4.90	229	<0.01	0.16
	Yes	80	3.44	1.22				
Received financial assistance	No	170	2.92	1.21	-0.46	232	0.65	0.18
	Yes	64	3.00	1.21				
Spent money OOP on item								
Insulin	No	74	2.70	1.23	-2.15	228	0.03	0.17
	Yes	156	3.06	1.19				
Testing strips	No	77	2.71	1.23	-2.06	230	0.04	0.17
	Yes	155	3.06	1.18				
Needles or syringes	No	124	2.67	1.18	-3.95	226	<0.01	0.16
	Yes	104	3.29	1.17				
Insulin pump supplies	No	169	2.95	1.24	0.38	224	0.71	0.19
	Yes	57	2.88	1.12				
CGM supplies	No	182	2.92	1.22	-0.16	224	0.87	0.20
	Yes	44	2.95	1.14				
Glucagon	No	199	2.93	1.19	0.36	226	0.72	0.24
	Yes	29	2.85	1.33				

Note: PFB=Perceived Financial Burden, OOP=Out-of-pocket, CGM=Continuous Glucose Monitor

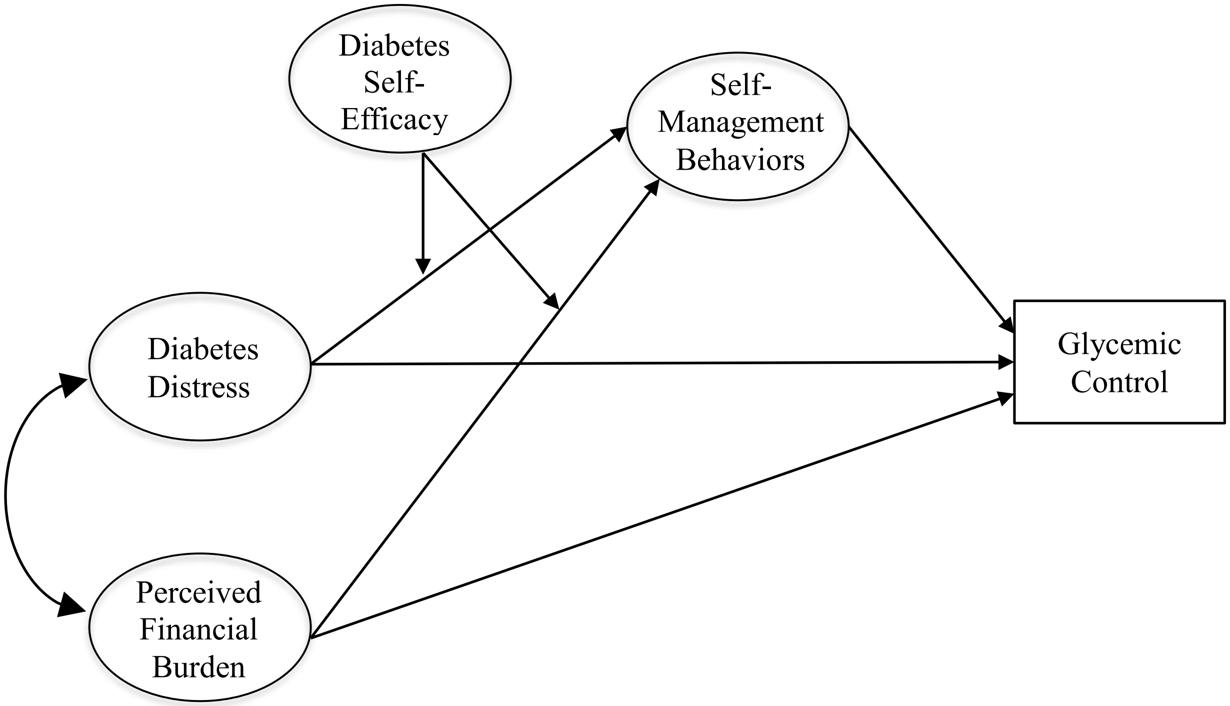


Figure 1. The conceptual model and hypothesized structural model, adapted from the Diabetes Resilience Model (Hilliard et al., 2012). Diabetes distress, perceived financial burden, diabetes self-efficacy, and diabetes self-management behaviors are latent constructs. Glycemic control, measured as self-report A1C, is an observed variable. Variance terms, error terms, and indicators are not shown.

Appendix A
Consent Form

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Type 1 Diabetes Management
VCU IRB NO.: HM20010826
INVESTIGATOR: Maria Thomson, PhD

If any information contained in this consent form is not clear, please ask the study staff to explain any information that you do not fully understand. You may keep a copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this study is to gain better understanding of experiences and needs of adults with type 1 diabetes. You are being asked to participate in this study because you have type 1 diabetes and you have received care at VCU Health within the previous 24 months. Approximately 400 individuals will participate in this study.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to complete one survey after you have had all your questions answered and understand what you will be asked to do. The survey will take approximately 15 minutes to complete. The survey includes questions about your health history, demographics, and your attitudes and experiences with managing type 1 diabetes.

In addition to answering these questions, you have the option of whether or not you authorize our research team to obtain the date(s) and result(s) of Hemoglobin A1C laboratory tests you have received at VCU Health within the previous twenty-four months, which would be accessed from your electronic medical record at VCU Health. Hemoglobin A1C is a blood test that estimates a person's average blood glucose over the previous three months. A question on the survey will ask you to indicate whether or not you authorize us to access that information. If you authorize us to access this information, your survey responses will be linked with your A1C test results.

RISKS AND DISCOMFORTS

There are minimal risks associated with your participation in the study. It is possible that you will be uncomfortable answering certain survey questions, but you may skip any questions and stop completing the questionnaire at any time. There is also a small risk that others outside the research team will learn about your confidential information. Please see the sections below about efforts we will make to protect your privacy and confidentiality.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information

The following people and/or groups may request my Protected Health Information:

- Principal Investigator and Research Staff
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Study Sponsor
- Institutional Review Boards
- Government/Health Agencies

Approved by the VCU IRB on 9/18/2017

Authority to Release Protected Health Information
The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUHS
- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released
The following types of information may be used for the conduct of this research:
☒ Diagnosis & treatment codes
☒ Laboratory test results
☒ Survey responses about your diabetes, diabetes management, and insurance status

Expiration of This Authorization
☒ This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Right to Revoke Authorization and Re-disclosure
You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

BENEFITS TO YOU AND OTHERS
You may not get any direct benefit from this study, but the information we learn from people in this study may help us design better programs to support adults with type 1 diabetes.

COSTS
There are no costs for participating in this study other than the time you will spend filling out the questionnaire.

PAYMENT FOR PARTICIPATION
If you choose to complete the survey, you will be entered into a draw for an iPad Air.

CONFIDENTIALITY
Potentially identifiable information about you will consist of your survey responses and the dates and results of any Hemoglobin A1C tests you have had done at VCU Health System, if you authorize the release of this information from your electronic medical record. Data is being collected only for research purposes.

We will not tell anyone the answers you give us, but information from the study and information from your medical record may be looked at or copied for research or by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services or other federal regulatory bodies as required by law.

At the beginning of the study you will be given a unique study number. Data we collect from you will be labeled using your study number, not your name. All personal identifying information will be kept separate from the research data in password-protected or locked files, and these files will be deleted at the end of this study. Data that does not have personal identifiers will be kept indefinitely. Access to all data will be limited to study personnel. What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this study. If you do participate, you may freely withdraw from the study at any time. Your decision to not participate or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. You may also choose not to answer particular questions you are asked in the study.

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Maria Thomson
Assistant Professor, Health Behavior and Policy
Virginia Commonwealth University
830 E. Main Street, 4th floor, PO Box 980149
Richmond, VA 23298
804-628-2640
Maria.thomson@vcuhealth.org

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

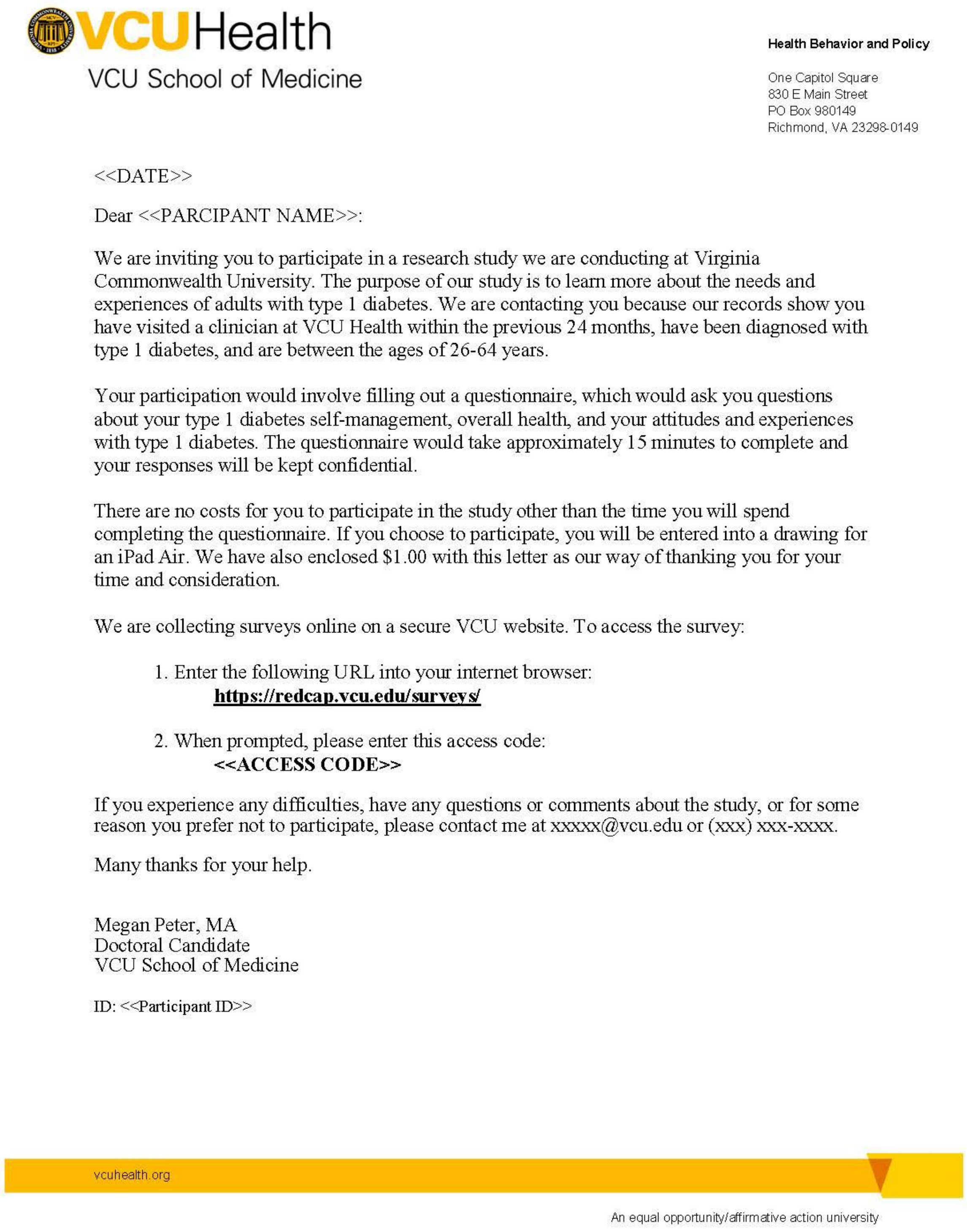
If you have any general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/human_research/volunteers.htm.

Appendix B
Letters and Emails to Participants

Contact 1: Letter to participants in mail and email conditions



VCUHealth
VCU School of Medicine

Health Behavior and Policy

One Capitol Square
830 E Main Street
PO Box 980149
Richmond, VA 23298-0149

<<DATE>>

Dear <<PARCIPANT NAME>>:

We are inviting you to participate in a research study we are conducting at Virginia Commonwealth University. The purpose of our study is to learn more about the needs and experiences of adults with type 1 diabetes. We are contacting you because our records show you have visited a clinician at VCU Health within the previous 24 months, have been diagnosed with type 1 diabetes, and are between the ages of 26-64 years.

Your participation would involve filling out a questionnaire, which would ask you questions about your type 1 diabetes self-management, overall health, and your attitudes and experiences with type 1 diabetes. The questionnaire would take approximately 15 minutes to complete and your responses will be kept confidential.

There are no costs for you to participate in the study other than the time you will spend completing the questionnaire. If you choose to participate, you will be entered into a drawing for an iPad Air. We have also enclosed $1.00 with this letter as our way of thanking you for your time and consideration.

We are collecting surveys online on a secure VCU website. To access the survey:

1. Enter the following URL into your internet browser:
   https://redcap.vcu.edu/surveys/
2. When prompted, please enter this access code:
   <<ACCESS CODE>>

If you experience any difficulties, have any questions or comments about the study, or for some reason you prefer not to participate, please contact me at xxxxx@vcu.edu or (xxx) xxx-xxxx.

Many thanks for your help.

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine

ID: <<Participant ID>>

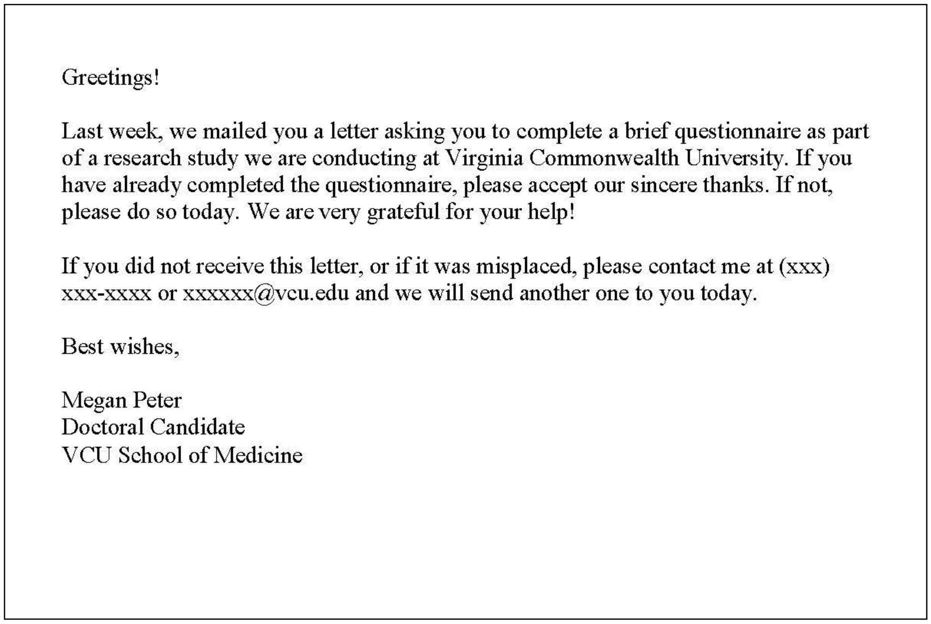
vcuhealth.org

Contact 2: Postcard to participants in mail condition

VCUHealth
VCU School of Medicine

Department of Health Behavior and Policy
830 E Main Street
PO Box 980149
Richmond, VA 23298-0149

<<Participant name>>
<<Address>>
<<City>>, <<State>> <<Zip>>



Greetings!

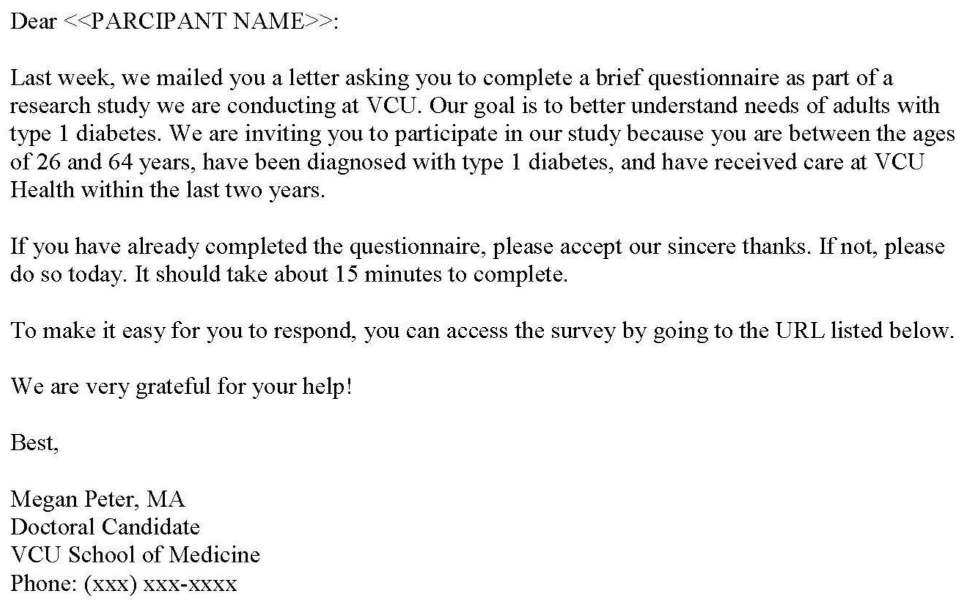
Last week, we mailed you a letter asking you to complete a brief questionnaire as part of a research study we are conducting at Virginia Commonwealth University. If you have already completed the questionnaire, please accept our sincere thanks. If not, please do so today. We are very grateful for your help!

If you did not receive this letter, or if it was misplaced, please contact me at (xxx) xxx-xxxx or xxxxxx@vcu.edu and we will send another one to you today.

Best wishes,

Megan Peter
Doctoral Candidate
VCU School of Medicine

Contact 2: Email to participants in email condition



Dear <<PARCIPANT NAME>>:

Last week, we mailed you a letter asking you to complete a brief questionnaire as part of a research study we are conducting at VCU. Our goal is to better understand needs of adults with type 1 diabetes. We are inviting you to participate in our study because you are between the ages of 26 and 64 years, have been diagnosed with type 1 diabetes, and have received care at VCU Health within the last two years.

If you have already completed the questionnaire, please accept our sincere thanks. If not, please do so today. It should take about 15 minutes to complete.

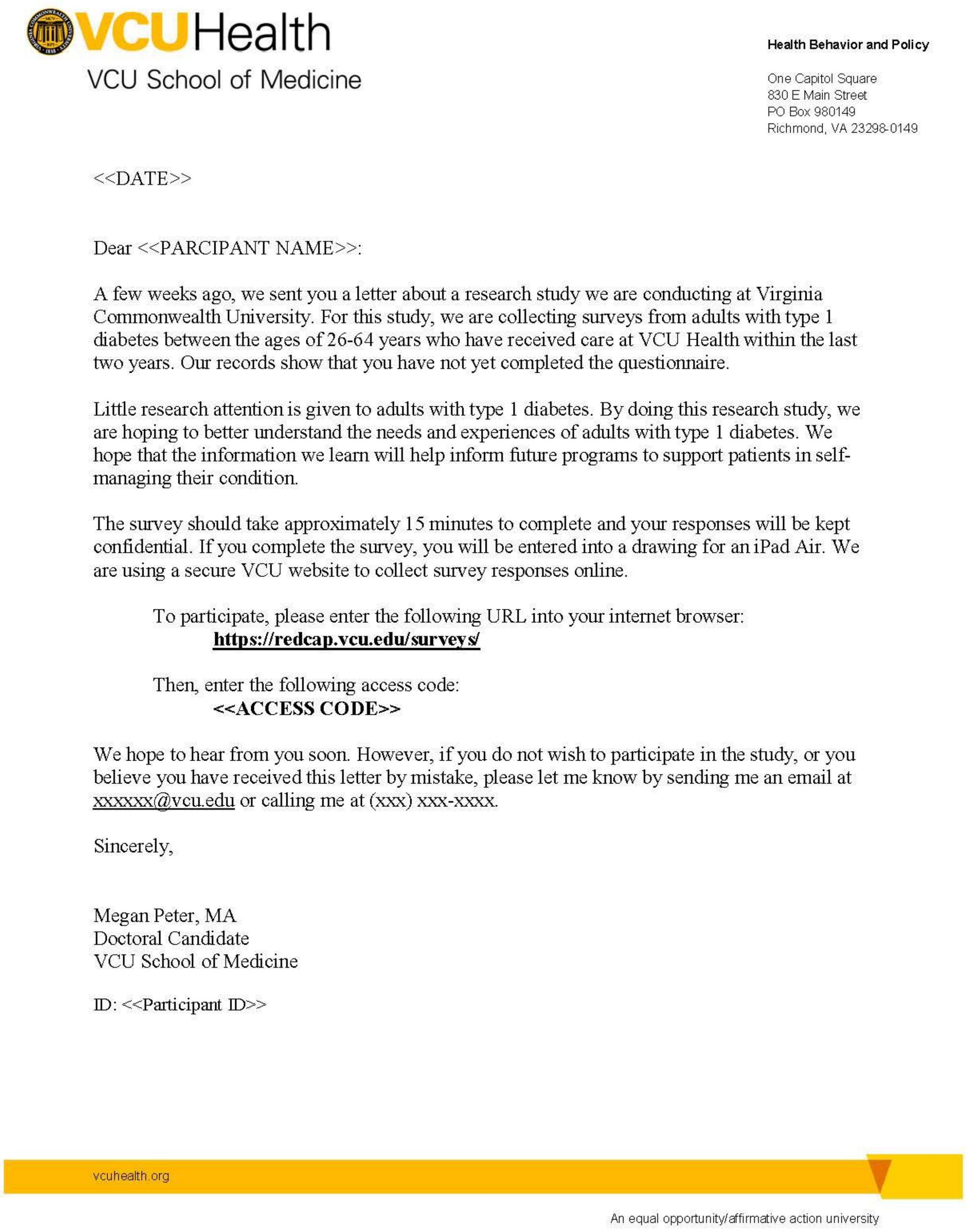
To make it easy for you to respond, you can access the survey by going to the URL listed below.

We are very grateful for your help!

Best,

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine
Phone: (xxx) xxx-xxxx

Contact 3: Letter to participants in mail condition



VCUHealth
VCU School of Medicine

Health Behavior and Policy

One Capitol Square
830 E Main Street
PO Box 980149
Richmond, VA 23298-0149

<<DATE>>

Dear <<PARCIPANT NAME>>:

A few weeks ago, we sent you a letter about a research study we are conducting at Virginia Commonwealth University. For this study, we are collecting surveys from adults with type 1 diabetes between the ages of 26-64 years who have received care at VCU Health within the last two years. Our records show that you have not yet completed the questionnaire.

Little research attention is given to adults with type 1 diabetes. By doing this research study, we are hoping to better understand the needs and experiences of adults with type 1 diabetes. We hope that the information we learn will help inform future programs to support patients in self-managing their condition.

The survey should take approximately 15 minutes to complete and your responses will be kept confidential. If you complete the survey, you will be entered into a drawing for an iPad Air. We are using a secure VCU website to collect survey responses online.

To participate, please enter the following URL into your internet browser:
https://redcap.vcu.edu/surveys/

Then, enter the following access code:
<<ACCESS CODE>>

We hope to hear from you soon. However, if you do not wish to participate in the study, or you believe you have received this letter by mistake, please let me know by sending me an email at xxxxxx@vcu.edu or calling me at (xxx) xxx-xxxx.

Sincerely,

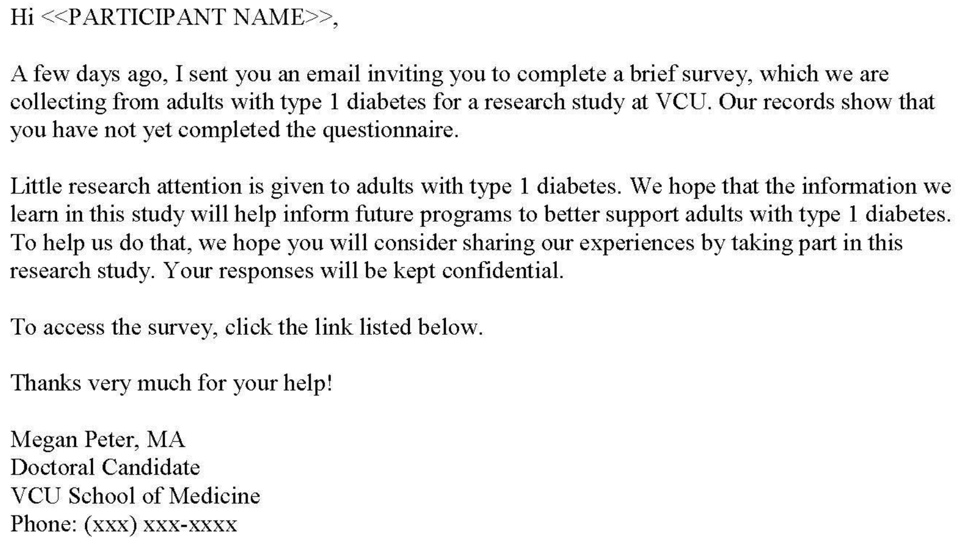
Megan Peter, MA
Doctoral Candidate
VCU School of Medicine

ID: <<Participant ID>>

vcuhealth.org

An equal opportunity/affirmative action university

Contact 3: Email to participants in email condition



Hi <<PARTICIPANT NAME>>,

A few days ago, I sent you an email inviting you to complete a brief survey, which we are collecting from adults with type 1 diabetes for a research study at VCU. Our records show that you have not yet completed the questionnaire.

Little research attention is given to adults with type 1 diabetes. We hope that the information we learn in this study will help inform future programs to better support adults with type 1 diabetes. To help us do that, we hope you will consider sharing our experiences by taking part in this research study. Your responses will be kept confidential.

To access the survey, click the link listed below.

Thanks very much for your help!

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine
Phone: (xxx) xxx-xxxx

Contact 4: Letter to participants in mail condition

VCUHealth
VCU School of Medicine

Health Behavior and Policy

One Capitol Square
830 E Main Street
PO Box 980149
Richmond, VA 23298-0149

<<DATE>>

Dear <<PARCIPANT NAME>>:

Over the past few weeks, our research team at VCU has sent you a few letters about a survey we are collecting from adults with type 1 diabetes for a research study. The purpose of this research is to learn more about factors that make it easier or more difficult for adults with type 1 diabetes to self-manage their condition. Not only will this information help advance scientific knowledge, we hope that our findings will help researchers develop programs to support adults with type 1 diabetes in achieving positive health outcomes.

Although many people have completed the survey, we have not heard from you. Our goal is to hear from almost everyone so that we can collect the most information about the experiences and challenged faced by adults with type 1 diabetes. We hope that you will consider taking part in this important research.

To make it easier for you to participate, we have enclosed a paper-and-pencil questionnaire. It should take about fifteen minutes to complete. Simply fill out the survey and return it to us using the postage-paid return envelope. If you choose to participate, you will be entered into a drawing for an iPad Air, as our way of thanking you for your time and assistance.

Maintaining confidentiality is very important to us. Please do not write your name or address on the survey or the return envelope. Instead, we have labeled questionnaires with a unique participant ID so that we can keep track of who responds. If you participate in the study, your survey responses will be completely separated from your name and any other identifiable information. We will publish aggregate findings in scientific journals, but not your name.

Please call or email me if you have any questions or concerns about our study. If you decide you are not interested in participating, and you do not wish to receive future contacts from our research team, please call or email me to let me know.

Best,

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine
(xxx) xxx-xxxx
xxxxxx@vcu.edu

ID: <<Participant ID>>

vcuhealth.org

Contact 4: Letter to participants in email condition

VCUHealth
VCU School of Medicine

Health Behavior and Policy

One Capitol Square
830 E Main Street
PO Box 980149
Richmond, VA 23298-0149

<<DATE>>

Dear <<PARCIPANT NAME>>:

Over the past few weeks, our research team at VCU has sent you a few letters and emails about a survey we are collecting from adults with type 1 diabetes for a research study. The purpose of this research is to learn more about factors that make it easier or more difficult for adults with type 1 diabetes to self-manage their condition. Not only will this information help advance scientific knowledge, we hope that our findings will help researchers develop programs to support adults with type 1 diabetes in achieving positive health outcomes.

Although many people have completed the survey, we have not heard from you. Our goal is to hear from almost everyone so that we can collect the most information about the experiences and challenged faced by adults with type 1 diabetes. We hope that you will consider taking part in this important research.

To make it easier for you to participate, we have enclosed a paper-and-pencil questionnaire. It should take about fifteen minutes to complete. Simply fill out the survey and return it to us using the postage-paid return envelope. If you choose to participate, you will be entered into a drawing for an iPad Air as our way of thanking you for your time and assistance.

Maintaining confidentiality is very important to us. Please do not write your name or address on the survey or the return envelope. Instead, we have labeled questionnaires with a unique participant ID so that we can keep track of who responds. If you participate in the study, your survey responses will be completely separated from your name and any other identifiable information. We will publish aggregate findings in scientific journals, but not your name.

Please call or email me if you have any questions or concerns about our study. If you decide you are not interested in participating, and you do not wish to receive future contacts from our research team, please call or email me to let me know.

Best,

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine
(xxx) xxx-xxxx
xxxxxx@vcu.edu

<<Participant ID>>

vcuhealth.org

An equal opportunity/affirmative action university

Contact 5: Letter to participants in mail condition

VCU Health
VCU School of Medicine

Health Behavior and Policy

One Capitol Square
830 E Main Street
PO Box 980149
Richmond, VA 23298-0149

<<DATE>>

Dear <<PARTICIPANT NAME>>:

Over the past few weeks, we have sent you a few letters about a research study we are conducting at Virginia Commonwealth University. The goal of our research is to learn more about the experiences and needs of adults with type 1 diabetes.

Our study is soon drawing to a close, so we just wanted to contact you one final time and give you an opportunity to participate in this research study by completing a 15-minute survey. We would love to hear from you.

If you are interested in participating, please complete and return the paper-and-pencil survey we previously mailed to you. Alternatively, you can complete the survey online by going to **https://redcap.vcu.edu/surveys/** and entering the following access code: **<<ACCESS CODE>>**

Thanks very much for your time and consideration. We wish you all the best.

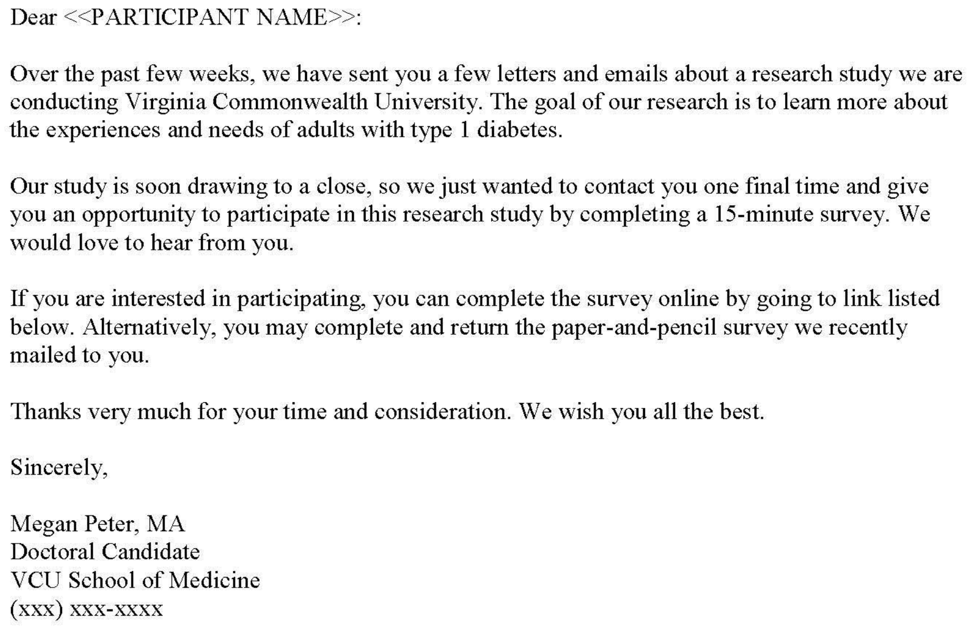
Sincerely,

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine
(xxx) xxx-xxxx
xxxxxx@vcu.edu

<<Participant ID>>

vcuhealth.org

Contact 5: Email to participants in email condition



Dear <<PARTICIPANT NAME>>:

Over the past few weeks, we have sent you a few letters and emails about a research study we are conducting Virginia Commonwealth University. The goal of our research is to learn more about the experiences and needs of adults with type 1 diabetes.

Our study is soon drawing to a close, so we just wanted to contact you one final time and give you an opportunity to participate in this research study by completing a 15-minute survey. We would love to hear from you.

If you are interested in participating, you can complete the survey online by going to link listed below. Alternatively, you may complete and return the paper-and-pencil survey we recently mailed to you.

Thanks very much for your time and consideration. We wish you all the best.

Sincerely,

Megan Peter, MA
Doctoral Candidate
VCU School of Medicine
(xxx) xxx-xxxx

Appendix C
Questionnaire

Type 1 Diabetes Management Survey

Section A. The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the ***past month***, please specify how much each statement applies to you by circling the appropriate number.

	Not at all	Somewhat	Considerably	Very much
1. I check my blood sugar levels with care and attention.	1	2	3	4
2. The food I choose to eat makes it easy to achieve optimal blood sugar levels.	1	2	3	4
3. I attend all doctors' appointments recommended for my diabetes treatment.	1	2	3	4
4. I take my insulin as prescribed.	1	2	3	4
5. I record my blood sugar levels regularly (or analyze the value chart with my blood glucose meter).	1	2	3	4
6. I do regular physical activity to achieve optimal blood sugar levels.	1	2	3	4
7. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	1	2	3	4
8. Occasionally I eat lots of sweets or other foods rich in carbohydrates.	1	2	3	4
9. I tend to avoid diabetes-related doctors' appointments.	1	2	3	4
10. I do *not* check my blood sugar frequently enough to achieve good blood glucose control.	1	2	3	4
11. I avoid physical activity, although it would improve my diabetes.	1	2	3	4
12. I tend to skip or forget to take my insulin.	1	2	3	4
13. Sometimes I have real 'food binges' (not triggered by hypoglycemia).	1	2	3	4
14. Regarding my diabetes care, I should see my medical practitioner(s) more often.	1	2	3	4
15. I tend to skip planned physical activity.	1	2	3	4
16. My diabetes self-care is poor.	1	2	3	4

Section B. Circle the number which is the closest to how you have been feeling over the past month.

Over the last month…	At no time	Some of the time	Less than half of the time	More than half of the time	Most of the time	All of the time
1. I have felt cheerful and in good spirits.	1	2	3	4	5	6
2. I have felt calm and relaxed.	1	2	3	4	5	6
3. I have felt active and vigorous.	1	2	3	4	5	6
4. I woke up feeling fresh and rested.	1	2	3	4	5	6
5. My daily life has been filled with things that interest me.	1	2	3	4	5	6

(continue to next page…)

Section C. Listed below are a variety of things that many people with type 1 diabetes experience. Thinking back over the ***past month***, please indicate the degree to which each of the following may have been a problem for you by circling the appropriate number.

	Not a problem	Slight problem	Moderate problem	Somewhat serious problem	Serious problem	Very serious problem
1. Feeling that I am not as skilled at managing diabetes as I should be.	1	2	3	4	5	6
2. Feeling that I don't eat as carefully as I probably should.	1	2	3	4	5	6
3. Feeling that I don't notice the warning signs of hypoglycemia as well as I used to.	1	2	3	4	5	6
4. Feeling that people treat me differently when they find out I have diabetes.	1	2	3	4	5	6
5. Feeling discouraged when I see high blood glucose numbers that I can't explain.	1	2	3	4	5	6
6. Feeling that my family and friends make a bigger deal out of diabetes than they should.	1	2	3	4	5	6
7. Feeling that I can't tell my diabetes doctor what is really on my mind.	1	2	3	4	5	6
8. Feeling that I am not taking as much insulin as I should.	1	2	3	4	5	6
9. Feeling that there is too much diabetes equipment and stuff I must always have with me.	1	2	3	4	5	6
10. Feeling like I have to hide my diabetes from other people.	1	2	3	4	5	6

	Not a problem	Slight problem	Moderate problem	Somewhat serious problem	Serious problem	Very serious problem
11. Feeling that my friends and family worry more about hypoglycemia than I want them to.	1	2	3	4	5	6
12. Feeling that I don't check my blood glucose level as often as I probably should.	1	2	3	4	5	6
13. Feeling worried that I will develop serious long-term complications no matter how hard I try.	1	2	3	4	5	6
14. Feeling that I don't get help I really need from my diabetes doctor about managing diabetes.	1	2	3	4	5	6
15. Feeling frightened that I could have a serious hypoglycemic event when I'm asleep.	1	2	3	4	5	6
16. Feeling that thoughts about food and eating control my life.	1	2	3	4	5	6
17. Feeling that my friends or family treat me as if I were more fragile or sicker than I really am.	1	2	3	4	5	6

(this section continued on next page…)

(*section continued from previous page*)	Not a problem	Slight problem	Moderate problem	Somewhat serious problem	Serious problem	Very serious problem
18. Feeling that my diabetes doctor doesn't really understand what it's like to have diabetes.	1	2	3	4	5	6
19. Feeling concerned that diabetes may make me less attractive to employers.	1	2	3	4	5	6
20. Feeling that my friends or family act like “diabetes police” (bother me too much).	1	2	3	4	5	6
21. Feeling that I’ve got to be perfect with my diabetes management.	1	2	3	4	5	6
22. Feeling frightened that I could have a serious hypoglycemic event while driving.	1	2	3	4	5	6
23. Feeling that my eating is out of control.	1	2	3	4	5	6
24. Feeling that people will think less of me if they knew I had diabetes.	1	2	3	4	5	6
25. Feeling that no matter how hard I try with my diabetes, it will never be good enough	1	2	3	4	5	6
26. Feeling that my diabetes doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
27. Feeling that I can’t ever be safe from the possibility of a serious hypoglycemic event.	1	2	3	4	5	6
28. Feeling that I don’t give my diabetes as much attention as I probably should.	1	2	3	4	5	6

Section D. The following questions ask about how your diabetes impacts different parts of your life.

	Very negative impact	Negative impact	Slightly negative impact	No impact	Slightly positive impact	Positive impact	Very positive impact
1. How much does your diabetes impact **your physical health**?	1	2	3	4	5	6	7
2. How much does your diabetes impact **your emotional wellbeing**?	1	2	3	4	5	6	7
3. How much does your diabetes impact **your leisure activities**?	1	2	3	4	5	6	7
4. How much does your diabetes impact **your financial situation**?	1	2	3	4	5	6	7
5. How much does your diabetes impact **your relationships with family, friends, and peers**?	1	2	3	4	5	6	7
6. How much does your diabetes impact **your work or studies**? (Select N/A if you do not currently work or attend school) ○ N/A	1	2	3	4	5	6	7

(continue to next page…)

Section E. Circle the number that indicates how much you agree or disagree with each statement.

In general, I believe that…	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
1. I know what part(s) of taking care of my diabetes that I am dissatisfied with	1	2	3	4	5
2. I am able to turn my diabetes goals into a workable plan.	1	2	3	4	5
3. I can try out different ways of overcoming barriers to my diabetes goals.	1	2	3	4	5
4. I can find ways to feel better about having diabetes	1	2	3	4	5
5. I know the positive ways I cope with diabetes-related stress	1	2	3	4	5
6. I can ask for support for having and caring for my diabetes when I need it	1	2	3	4	5
7. I know what helps me stay motivated to care for my diabetes.	1	2	3	4	5
8. I know enough about myself as a person to make diabetes care choices that are right for me.	1	2	3	4	5

Section F. Consider the money you spend on your diabetes medication, supplies, and healthcare. Indicate how much you agree or disagree with each statement by circling the appropriate number.

	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
1. Cost is a problem in managing my diabetes.	1	2	3	4	5
2. My financial resources are adequate to pay for things that are required for diabetes.	1	2	3	4	5
3. It is difficult to pay for the things I need for my diabetes.	1	2	3	4	5
4. Caring for diabetes puts a financial strain on me.	1	2	3	4	5
5. Because of costs, I underuse diabetes supplies (e.g., insulin, continuous glucose monitor supplies).	1	2	3	4	5
6. Because of costs, I go to the doctor less frequently than I should.	1	2	3	4	5

(continue to next page…)

Section G. These questions ask about out-of-pocket costs of your diabetes expenses in the past 12 months.

Out-of-pocket costs refer to costs *not* paid by a health insurance company or financial assistance program. Indicate whether you have spent money out-of-pocket on each of the following items in the last 12 months. Select 'No' if the cost was completely paid for by your health insurance or a financial assistance program (e.g., if your copay or coinsurance was $0).

If No → Go to the question shown

If Yes→ Write how many times you bought the item in the last 12 months, and how much you paid for the item each time you bought it in the last 12 months. Please provide a ***single number***, not a range. If your out-of-pocket costs varied, please estimate the average amount you spent. ***All questions below are referring to the last 12 months***.

1. In the last 12 months, did you spend money out-of-pocket on **INSULIN**?

○ No→ If No, go to **#4**

○ Yes→ 2. About *how many times* did you spend money out-of-pocket on insulin? ______times

3. Each time you spent money on insulin, about how much did you spend? ______dollars

4. In the last 12 months, did you spend money out-of-pocket on **TEST STRIPS?**

○ No→ If No, go to **#7**

○ Yes→ 5. About *how many times* did you spend money out-of-pocket on test strips? ______times

6. Each time you spent money on test strips, about how much did you spend? ______dollars

7. In the last 12 months, did you spend money out-of-pocket on **NEEDLES OR SYRINGES?**

○ No→ If No, go to **#10**

○ Yes→ 8. About *how many times* did you spend money out-of-pocket on needles/syringes? ______times

9. Each time you spent money on needles/syringes, about how much did you spend? ______dollars

10. In the last 12 months, did you spend money out-of-pocket on **INSULIN PUMP SUPPLIES?**

○ No→ If No, go to **#13**

○ Yes→ 11. About how many times did you spend money out-of-pocket on pump supplies? ______times

12. Each time you spent money on pump supplies, about how much did you spend? ______dollars

13. In the last 12 months, did you spend money out-of-pocket on **CGM SUPPLIES (e.g., sensors)?** (*CGM refers to continuous glucose monitor*)

○ No→ If No, go to **#16**

○ Yes→ 14. About *how many times* did you spend money on CGM supplies? ______times

15. Each time you spent money on CGM supplies, about how much did you spend? ______dollars

16. In the last 12 months, did you spend money out-of-pocket on **GLUCAGON?** (*Glucagon is an emergency injection kit for low blood sugar*)

○ No→ If No, go to **#19**

○ Yes→ 17. About *how many times* did you spend money out-of-pocket on glucagon? ______times

18. Each time you spent money on glucagon, about how much did you spend? ______dollars

19. In the last 12 months, did you discuss diabetes costs with your healthcare provider?

○ No

○ Yes

20. In the last 12 months, did you receive free or discounted diabetes supplies through a financial assistance program (e.g., for insulin or testing strips)?

○ No

○ Yes

(continue to next page…)

Section H. Select or circle your responses to the following questions. When a blank line is provided, write in your response to the question.

1. Do you currently have health insurance?
   - ○ Yes
   - ○ No→ **If No, go to #7**

2. Which of the following describes your current health insurance plan(s)?
   - ☐ Private health insurance (through an employer)
   - ☐ Private health insurance (individual plan)
   - ☐ Medicaid
   - ☐ Medicare
   - ☐ Military healthcare (e.g., Tri-Care, VA)
   - ☐ Virginia Coordinated Care
   - ☐ Other:________________________ (Specify)

3. Does your health insurance offer benefits or cover services that meet your needs?
   - ○ Always
   - ○ Usually
   - ○ Sometimes
   - ○ Never

4. Are the costs not covered by your health insurance reasonable?
   - ○ Always
   - ○ Usually
   - ○ Sometimes
   - ○ Never

5. Does your health insurance allow you to see the health care providers you need?
   - ○ Always
   - ○ Usually
   - ○ Sometimes
   - ○ Never

6. If you had the chance, would you switch to a different health care plan?
   - ○ Definitely no
   - ○ Probably no
   - ○ Probably yes
   - ○ Definitely yes

7. At what age were you diagnosed with type 1 diabetes? ______ years old

8. How do you currently treat your diabetes?
   - ○ Insulin pump
   - ○ Multiple daily injections

9. Do you use a continuous glucose monitor?
   - ○ Yes
   - ○ No

10. Have you ever been diagnosed with the following conditions? Select all that apply.
    - ☐ Sleeping problems
    - ☐ Eye damage (diabetic retinopathy)
    - ☐ Depression
    - ☐ Nerve damage (diabetic neuropathy)
    - ☐ Sexual dysfunction
    - ☐ Foot ulcers
    - ☐ Kidney disease (nephropathy)
    - ☐ Heart disease

11. Have you ever experienced seizure or loss of consciousness from *low blood sugar (hypoglycemia)*?
    - ○ Yes
    - ○ No

12. Have you ever had *diabetic ketoacidosis* (DKA) diagnosed by a doctor that required treatment at a healthcare facility?
    - ○ Yes
    - ○ No

13. In the last 12 months, *how many times* have you experienced seizure or loss of consciousness from low blood sugar (hypoglycemia)? ______time(s)

14. In the last 12 months, how many times have you had *diabetic ketoacidosis* diagnosed by a doctor that required treatment at a healthcare facility? ______time(s)

15. When was your most recent Hemoglobin A1C blood test? Please provide the month and year (for example: 05/2017). ______/_______ month year

16. What was the result of your most recent A1C test (e.g., 7.0 or 8.9)? ________%

(continue to next page…)

17. What is your gender?
    - ○ Male
    - ○ Female

18. What is the highest level of education you have completed?
    - ○ Did not complete high school
    - ○ High school diploma or GED
    - ○ Some college but no degree
    - ○ Associate's degree
    - ○ Bachelor's degree (BA, BS)
    - ○ Master's degree (MBA, MA, MSW)
    - ○ Doctorate/professional degree (MD, PhD, JD)

19. What is your annual household income?
    - ○ Less than $25,000
    - ○ $25,000-34,999
    - ○ $35,000-49,999
    - ○ $50,000-74,999
    - ○ $75,000-99,999
    - ○ $100,000 or more
    - ○ Prefer not to answer

20. What is your employment status?
    - ○ Not working
    - ○ Working part-time
    - ○ Working full-time

21. What is your race/ethnicity? Select one or more.
    - ☐ White or Caucasian (Non-Hispanic)
    - ☐ African American or Black (Non-Hispanic)
    - ☐ Hispanic or Latino/a
    - ☐ Asian
    - ☐ Native American or American Indian
    - ☐ Other (specify:)____________________

22. What is your marital status?
    - ☐ Single (never married, not living with partner)
    - ☐ Living with partner, not married
    - ☐ Married
    - ☐ Separated or divorced
    - ☐ Widowed

23. Including yourself, how many people live in your household? ______ people

24. What is your age? ______ years

25. What is your weight? ______ pounds

26. What is your height? _____feet ______inches

Authorization to Access A1C Results from Electronic Medical Records

There are two types of information we are collecting from participants in this study:

(1) Responses to questions in this survey, and
(2) Results of previous Hemoglobin A1C blood tests, which will be collected from electronic medical records. (*A1C is a blood test that estimates someone's average blood glucose over the previous two to three months*).

In addition to answering questions in the survey, you also have the option of allowing us to access A1C test results from the last 24 months from your electronic medical records at VCU Health. Participants' A1C results will be linked with their survey responses, so that we can analyze which factors are related to participants' blood glucose levels.

Please note that any information you give us will be kept confidential. After we have collected survey responses and A1C test results, all data will be separated from participants' names and other identifying information.

27. ***Please select one of the following options:***

    - ○ **Yes**—I authorize the researchers to access the date(s) and result(s) of A1C tests I have received in the previous 24 months from my electronic medical records at VCU Health.
    - ○ **No**—I do not authorize the researchers to access A1C test results from my electronic medical records at VCU Health.

iPad Drawing

All participants who respond to the survey may be entered into a drawing for an iPad Air, regardless of whether you authorize us to access your A1C test results from your electronic medical records.

28. Would you like to be entered into the drawing for an iPad Air?
    - ○ Yes
    - ○ No

Thank you for completing the survey. Please return your questionnaire using the enclosed postage-paid envelope.