BENEFITS OF BEHAVIORAL HEALTH INTERVENTION FOR GLYCEMIC CONTROL IN PEDIATRIC AND YOUNG ADULT PATIENTS WITH TYPE 1 DIABETES

By

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Abstract

Management of type 1 diabetes (T1D) requires daily and intensive self-care behaviors that include frequent monitoring of diet, blood glucose, and insulin doses. Treating T1D is especially complex and often stressful for young patients and their families. Youth with T1D, along with their caregivers, must work together to maintain adequate glycemic control while navigating the biological and psychosocial changes inherent to child and adolescent development. Advances in diabetes technology, such as continuous glucose monitors and automated insulin pumps, promise positive health outcomes. However, despite these technological gains, fewer than 25% of adolescents with T1D have met the glycemic targets set by the American Diabetes Association (ADA) over the past decade. Thus, research indicates that behavioral and psychosocial factors are the primary barriers to optimal diabetes self-management. The aims of the current study were to 1) Evaluate associations between receipt of behavioral health intervention and longitudinal trends in glycemic control as measured by HbA1c, and 2) Evaluate the association of intervention dose on HbA1c.

Methods. This study utilized medical record data from 2008 to 2023 from the Harold Schnitzer Diabetes Health Center at Oregon Health & Science University. The sample comprised N = 314 patients aged 0-25 years with diagnoses of T1D and who met with a diabetes-specific psychologist at least twice. Mixed-methods regression models were utilized to understand linear, quadratic, and cubic trends in HbA1c prior to and following behavioral health intervention.

Results. In the full sample, as well as in subsamples with in-range or clinically elevated baseline HbA1c values, behavioral health intervention was significantly associated with HbA1c reduction, characterized by an initial steep decline followed by a slight rebound and subsequent

decrease. The number of behavioral intervention sessions with a pediatric psychologist was not significantly associated with trajectories of HbA1c in the full sample or either subsample.

Conclusion. The current study sought to characterize the association between receipt of behavioral health intervention and diabetes outcomes in real-world clinical settings. Results of this study confirm the importance of integrated behavioral treatment models in a specialized medical clinic. Future research should continue to explore differences in response to behavioral health intervention and retention methods to inform treatment models that address the needs of children and young adults with T1D.

Chapter 1: Introduction and Background

1.1 Type 1 Diabetes

Type 1 (insulin-dependent) diabetes is an organ-specific autoimmune disease in which human antibodies damage insulin-producing beta (ß) cells in pancreatic islet cells (Thompson et al., 2023). This destructive process, also known as islet cell autoimmunity, significantly reduces or eliminates insulin-producing beta cells (Kulkarni, 2004; Noble & Valdes, 2011). Breakthroughs in the understanding of type 1 diabetes (T1D) began in the 19th century, with seminal research by physician Joseph Von Mering and physiologist Oskar Minkwoski (1889) who first discovered that the removal of the pancreas contributed to diabetes in animal models. This study initiated the understanding of the pancreas' role in regulating blood glucose, and insulin's exogenous synthesis soon followed (Vecchio et al., 2018). The pathophysiology of T1D is now one of the most frequently studied complex genetic disorders in children (Concannon et al., 2009; Gale, 2002).

Decades of research into T1D have confirmed the key role of insulin in digestive and endocrine systems. In typically functioning digestive and endocrine systems, carbohydrates that are consumed are quickly broken down into glucose which enters the blood stream. Secondary to this process, functioning pancreases quickly secrete insulin, which binds to receptors on the surface of blood cells, allowing glucose to move into the cells and provide immediate energy (Vecchio et al., 2018; Wilcox, 2005). Insulin also stimulates glucose uptake in the muscle and adipose tissues, which is stored as energy for later periods of low blood-glucose levels (Chandel, 2021). In this way, adequate insulin secretion regulates blood-glucose levels quickly after carbohydrate consumption, and several hours after a meal. Without insulin-producing ß cells, carbohydrates are unable to be used immediately as energy immediately in cells, or stored for

later in the liver, fat, and muscles, which contributes to the maintenance of elevated blood-glucose levels.

While T1D can develop at any age, islet cell autoimmunity typically begins in early childhood, with incidences peaking in the second year of life. Research has shown that roughly seventy percent of children who develop islet antibodies progress to a diagnosis of diabetes over the next ten years, although diagnoses are most common between ages 4 to 6 years (Rewers & Ludvigsson, 2016; Ziegler et al., 2013). Younger age at diagnosis predicts poorer glycemic control, independent of known confounding risk factors such as duration of disease (Goldberg et al., 2021). Long-term health complications associated with T1D are also linked to age of diagnosis, with a 2018 study reporting that disease onset before 10 years of age is related to a 30- to 60-fold increase in risk of coronary heart disease and myocardial infarction later in life (Rawshani et al., 2018). Thus, understanding the factors that lead to the prevalence and successful, early management of T1D is crucial.

1.2 Prevalence of Pediatric Type 1 Diabetes

Incidence rates of pediatric T1D have been increasing in all parts of the world since the beginning of the 20th century (Gale, 2002). In 2021, an estimated 8.4 million individuals worldwide were living with T1D, with an estimated increase of 250,000 to 500,000 new cases per year (Abela & Fava, 2021; Ogrotis et al., 2023). Roughly 1.5 million of these individuals were between birth and 19 years of age (Gregory et al., 2022). Epidemiological research consistently shows a high rate of T1D in youth in the United States, with estimates ranging from 1 in every 300 to 4 in every 1000 youth (Fang et al., 2024; Maahs et al., 2010). Although the exact etiology of T1D remains highly debated, genetic predispositions are strongly implicated. Research suggests that unique alterations in human leukocyte antigens (HLA) are associated with

proinflammatory ß cell destruction (Noble & Valdes, 2011). Indeed, studies show that 75% to 90% of children with T1D have one of two unique combinations of HLA genes: DR_4-DQ_8 and DR_3-DQ_2 (Gillespie, 2006; Steck et al., 2011). However, research has also shown that T1D can be triggered by environmental factors among individuals who are genetically susceptible (Lucier & Mathias, 2024). Epigenetic mechanisms, or the way in which environment and lifestyles impact gene expression, have been hypothesized to describe both the increase in prevalence rates and progression of islet cell autoimmunity in T1D.

Changes in environments that trigger the progression of T1D may, in part, explain the global growth in incidence of T1D. Proposed triggers for the progression of islet cell autoimmunity to T1D include exposure to toxins in the perinatal period, infections, and diet (Gillespie, 2006; Rewers & Ludvigsson, 2016). Research suggests that viral infections and exposure to toxins early in life can trigger autoimmune responses that induce or accelerate islet cell destruction in individuals who are genetically susceptible (Christen et al., 2012). A multi-national, longitudinal study, The Environmental Determinants of Diabetes in the Young (TEDDY), which has been investigating environmental influences on the development of T1D since 2004, also points to several dietary factors that influence T1D development such as timing of solid food introduction and probiotic exposure (Uusitalo et al., 2023). Evidence for the support of exogenous factors in the prevalence of T1D is supported by monozygotic twin studies, which have shown that only 13% to 33% of twin pairs share the condition (Knip et al., 2005). These data bolster the role of perinatal and environmental factors in T1D development.

Additionally, there has been a disproportionate rise in prevalences of T1D among subpopulations. In the United States, youth who identify as ethnic and racial minorities have experienced significantly greater acceleration of T1D incidence rates in the last two decades

compared to their non-ethnic or -racial minority counterparts (Lawrence et al., 2012). Social determinants of health, including socioeconomic deprivation and decreased access to care, have been posited as frameworks to understand these disparities (Griggs et al., 2023). Premature mortality among youth with T1D is also greater in lower income countries (Gregory et al., 2022). Evidence from monozygotic twin studies, as well as the increase in prevalence in subpopulations, supports the hypothesis that islet cell autoimmunity may develop by a combination of genetic susceptibility and environmental exposures, or through an epigenetic effect. Furthermore, support for the heterogeneity of a manifestation of T1D by age, environmental factors, and genotypes is growing. While the exact processes associated with the global rise in the incidence of T1D are unknown, strategies to improve health outcomes are essential.

1.3 Hypoglycemia and Hyperglycemia

The objectives for managing TID in pediatric populations include promoting normal growth and development and mitigating long-term diabetes-related complications (Beck & Cogen, 2015). These objectives are complicated by two consequences of improper glucose management: hypoglycemia and hyperglycemia. Severe hypoglycemia and hyperglycemia contribute to disruptions in growth, development, and can have lasting effects on health. Hypoglycemia is characterized by a concentration of glucose in the blood that is lower-than-normal, typically defined (in populations without diabetes) by a blood glucose level less than 70mg/dL, with a level of less than 50mg/dL requiring emergency medical attention (Amiel, 2021). Conversely, hyperglycemia is defined as a higher-than-normal concentration of blood glucose, typically defined as levels greater than 120mg/dL. In populations with diabetes, blood glucose level goals range from 80mg/dL to 180mg/dL. See Table 1 for descriptions of hypoglycemic and

hyperglycemic thresholds. Hypoglycemia and hyperglycemia occur when individuals with T1D consume too few or too many carbohydrates, respectively, or when an individual administers a disproportionately high or low dose of insulin relative to the carbohydrates ingested.

Recurrent hypoglycemia and hyperglycemia have both acute and lasting implications for brain and bodily functions. Acute risks of hypoglycemia include cognitive slowing, irritability, drowsiness, seizures, comas, and sometimes death (Amiel, 2021). Additionally, frequent episodes of hypoglycemia initiate a process wherein the glucose concentration at which sympathetic and hormonal responses occur is downregulated, causing individuals to be less aware of a hypoglycemic event, which leads to a paradoxical increased risk of severe hypoglycemia (McCrimmon, 2021). Hypoglycemia unawareness occurs in roughly 25% of individuals with T1D and leads to a sixfold increase in severe hypoglycemia (Driscoll et al., 2016). Sequalae of recurrent hypoglycemia include increased risk of blood clotting, decreased blood vessel function, impaired cognition, and inflammatory responses (Amiel, 2021). Acute hyperglycemia is also associated with short-term effects such as polyuria, polydipsia, nausea, and diabetic ketoacidosis (DKA). More long-term risks associated with recurrent hyperglycemia include kidney disease (nephropathy), eye disease (retinopathy), nerve disorders (neuropathy), heart disease, and stroke (Giri et al., 2018).

Achieving and maintaining proper glycemic control is essential for long-term health outcomes and quality of life for individuals living with diabetes. Hypoglycemic seizures (caused by severely low blood sugar) and diabetic ketoacidosis (caused by severe hyperglycemia) are among the most severe, acute outcomes that produce long-term consequences for youth with T1D. To avoid these negative health outcomes, individuals with T1D are tasked with constant and daily attention to blood glucose levels. While proper insulin administration is the most

important regulator of glucose homeostasis, individuals with T1D must also manage this life-long disease with daily blood glucose monitoring and attention to diet and physical activity (Datye et al., 2015; Yari et al., 2020). Furthermore, in youth with T1D, due to normal growth and development, even proper diet and insulin administration can result in unstable blood glucose levels. Thus, treatment models emphasize the importance of blood glucose monitoring as the key self-care behavior for young patients (Harris et al., 2014). Avoiding the consequences of poor diabetes management in youth is dependent on these self-care behaviors and adherence to prescribed treatment regimens.

1.4 Blood Glucose and Hemoglobin A1c (HbA1c)

The effectiveness of T1D treatment is commonly estimated by the results of daily blood glucose testing and hemoglobin A1c (HbA1c) assays, a measure of estimated average glucose over the past three months. Blood glucose is tested by placing a small amount of blood on a specially treated test-strip, which is subsequently inserted into an electronic blood glucose meter that presents the results in either mg/dL or mmol/L units (Pickering & Marsden, 2014). Adequate blood glucose for diabetic youth falls between 80mg/dL and 180mg/dL. *Average* glycemic control is estimated by an HbA1c lab value. Table 2 depicts the estimated relationships between daily blood glucose levels and HbA1c values. The American Diabetes Association (ADA) has guidelines for determining optimal and suboptimal HbA1c values and recommends pediatric patients with diabetes maintain an HbA1c below 7.5%, with HbA1c levels less than 8.0% being acceptable (Committee, 2024)

While HbA1c values are a useful tool for estimating average blood glucose levels, the importance of daily, frequent self-monitoring of blood glucose has often been suggested as the primary goal for youth. Focusing on the self-care behavior of blood glucose checking, rather than

the actual, real-time value or HbA1c assays may be most helpful for younger patients (Harris et al., 2014). Indeed, studies have shown a significant correlation between frequent self-monitoring of blood glucose and lower HbA1c levels, with each additional test per day associated with a decrease of 0.2% in HbA1c (Nathan, 1993; Wang & Shah, 2016). Furthermore, frequent glucose monitoring (up to 10 times per day) is a consistent recommendation by the American Diabetes Association (ADA), that regularly updates its Standards of Care for children and adolescents with T1D to meet emerging evidence. The ADA Standards of Care also enumerate nutrition, physical activity, psychosocial support, and self-care education recommendations. Consuming a diet rich in protein, fibers, unsaturated fats, and natural sugars is associated with improved glycemic control and HbA1c outcomes in youth with T1D (Nansel et al., 2016). Physical activity in combination with proper insulin dosing and food intake is another important behavior associated with achieving clinically acceptable diabetes health outcomes (Colberg et al., 2015). Understandably, daily decisions for managing T1D are complex and burdensome. However, advances in medical technology have transformed patients' ability to properly manage their health condition.

Continuous glucose monitors (CGM), wearable insulin pumps, and telephone-based applications have reshaped patients' capacity to manage diabetes, and the effectiveness of these medical technologies are well established (Beck et al., 2017; Dovc et al., 2019; Tauschmann et al., 2020). Indeed, the ADA Standards of Care published in 2025 recommend real-time CGMs, insulin pumps, and automated insulin delivery (AID) systems be offered for all patients for diabetes management at the time of diagnosis or as soon as possible. In the case of pediatric patients with T1D, continuous glucose monitors also increase the ability to share glucose data with caregivers and one's clinical care team, improving the social and medical support patients

receive. In one retrospective study of 15,000 patients with T1D, ranging in age from 2-19 years, sharing data with a "follower" (family member or caregiver) was associated with significantly lower mean glucose values (Welsh et al., 2019). CGMs that are integrated with continuous insulin infusion pumps and "smart" pens that optimize insulin dosage further automate this process and reduce patient burden (Grunberger et al., 2021).

The utilization of technological and digital health tools has expanded dramatically since their gradual introduction beginning approximately 40 years ago (Sherr et al., 2016). A 2020 meta-analysis found that introducing continuous glucose monitoring and maintaining its regular use among children and adolescents with T1D was correlated with decreased instances of diabetic ketoacidosis and severe hypoglycemia (Tauschmann et al., 2020). The use of CGMs is also associated with significant psychological benefits in youth such as improved ratings of quality of life and decreased fear of hypoglycemia (Patton & Clements, 2016). However, despite well-established methods to manage diabetes and track adherence, only 21% of U.S. adolescents with T1D met glycemic goals set forth by the American Diabetes Association in 2015 (Datye et al., 2015). These data suggest the primary barriers to optimal diabetes self-care are not a lack of effective treatment or monitoring options. Instead, research suggests the primary barriers to optimal diabetes self-care are behavioral and/or psychosocial in nature (Wolfsdorf et al., 2006).

1.5 Psychosocial Barriers to Treatment Adherence in Type 1 Diabetes

Psychosocial barriers to treatment adherence in pediatric patients with T1D are numerous. Psychological barriers include untreated or undertreated mental health conditions (in particular, diabetes distress, fear of hypoglycemia, depression, anxiety, and eating disorders) (Bryden et al., 2001; Wagner et al., 2015). Lower parental education, poor health counseling, and poor access to medical services also predict poorer disease outcomes (Kalra et al., 2018; Naranjo

et al., 2016). Doubts about the efficacy of treatment, lack of self-efficacy in executing the diabetes self-care plan, lack of social support, and lack of socioeconomic resources are also related to risk of decreased glycemic control (Aljasem et al., 2001). Social determinants of health – such as geographic isolation, limited access to health counseling, and lower socioeconomic status – have been shown to predict poorer health outcomes across populations (Chen et al., 2019; Fehr et al., 2020). Longitudinal studies also suggest that the teenage years are associated with peaks in HbA1c, while emerging adulthood also poses challenge for treatment adherence when youth transfer to adult diabetes services (Bryden et al., 2001; Wagner et al., 2015). Each of these risk factors pose particularly problematic consequences for patients with T1D (Kirkman et al., 2015).

Unfortunately, achieving optimal self-care behaviors (and thus, health outcomes) among pediatric populations with T1D is particularly difficult. The ever-present tasks associated with managing T1D impose a significant burden (Harris et al., 2014). However, young individuals undergoing cognitive, psychological, social, and biological changes as a normal part of their growth and development, are faced with managing this disease dynamically. Researchers (Halvorson et al., 2005) have utilized a case study methodology to highlight the unique developmental considerations when treating this population. These authors argued that treatment plans often fall short with pediatric populations without a deeper exploration of unique barriers, such as growth and organ maturation, psychological characteristics, family dynamics, and care outside the home. Physiological studies, including cross-sectional observations and longitudinal studies in non-diabetic populations, consistently demonstrate that puberty is associated with a temporary decline in insulin sensitivity. This maturational time alters insulin requirements and complicates diabetes management in children and adolescents (Bloch et al., 1987; Hannon et al.,

2006). Changes in pediatric patients' cognitive and emotional ability to provide self-care also produces changes in health condition (Giordano et al., 1992). Furthermore, young patients with T1D have greater neurological vulnerability to hypoglycemia and hyperglycemia as well as the adverse neurocognitive effects of DKA (Committee, 2024). Attention to the regularly changing biopsychosocial and cognitive aspects of young individuals' lives has repeatedly been posited as a crucial elements to effective diabetes care in this population.

In appreciation of these unique treatment considerations, the ADA Standards of Care encourage developmentally appropriate family involvement in diabetes management tasks for children and adolescents. This seminal reference point for diabetes treatment providers recognizes that premature transfer of diabetes care responsibility to youth can result in higher rates of diabetes burnout, suboptimal diabetes management, and deterioration of glycemic control. Additionally, these standards encourage providers to ask youth and their caregivers about social adjustment (peer relationships) and school performance to determine whether further intervention is warranted. Ultimately, a key factor in the recommendations for management of T1D in youth put forth by the ADA is the role of psychosocial development**.**

1.6 Psychosocial Development and Management of Type 1 Diabetes

As opposed to adult disease management, pediatric disease management is complicated by stages of psychosocial development. Each developmental stage of early life is associated with its own advances that affect an individual's ability to manage their health. Developmental milestones that affect diabetes management include skill development, temperament changes, advances in abstract thinking, social influence, independence, and increased autonomous decision-making about meals, activity levels, and insulin administration (Oberklaid & Drever,

2011). Achieving positive health outcomes throughout development is therefore a dynamic process which includes considering the unique skills achieved in each patient's life.

One aspect to consider when examining a patient's readiness for independence in self-care is their cognitive and emotional development. Tasks related to managing diabetes can be intricate, often requiring substantial engagement of higher-level cognitive functions and regulation of emotions. The cognitive demands associated with self-care behaviors encompass various aspects such as planning, organization, initiation, flexibility in thinking, memory, vigilance, and emotional regulation (Duke & Harris, 2014). Findings of a comprehensive review suggested that greater cognitive abilities necessary for independent, intentional, and goal-oriented actions were related to improved treatment adherence and glycemic control (Duke & Harris, 2014).Furthermore, greater emotional processing abilities are associated with improved metabolic control in adolescents with T1D, underscoring the important role of emotion regulation in effective diabetes management (Hughes et al., 2012). Thus, the constant development of cognitive abilities and emotional regulation skills within adolescence is a relevant factor when considering diabetes management in youth.

The impact of the social stages of development is another key consideration in this population. Adolescence is a time of life in which individuals tend to establish autonomy, challenge authority, and seek increased independence (Commissariat et al., 2016). During this period, adolescents are more prone to seek out enjoyable experiences, place a higher importance on personal privacy, develop a stronger sense of self-identity, and are more susceptible to the influence of their peers. Multiple literature reviews support the finding that metabolic control often worsens during the pubertal years in individuals with T1D, and it is theorized that social factors significantly contribute to this change (Hamilton & Daneman, 2002; Harris et al., 2014).

Adolescents attempting to manage a challenging health condition during this phase of development must also navigate negative self-image related to being different from their peers (Helgeson et al., 2007). Ultimately, social factors inherent in maturing throughout developmental stages ("growing up") include juggling the different demands of diabetes management within the social spheres of their life including family, school, and peers. In general, supporting young patients' engagement in necessary self-care behaviors must consider relevant emotional, cognitive, and social developmental stages (Peyrot & Rubin, 2007). Attention to these factors is key to mitigating suboptimal physical and mental health outcomes associated with T1D.

1.7 Psychological Outcomes Associated with Type 1 Diabetes

The psychological burden of living with a chronic illness must also be considered as a potential barrier to positive health outcomes. Living with a chronic illness such as T1D has been shown to affect psychological well-being, social functioning, and overall quality of life. One cross sectional study of 49 children found that those with elevated HbA1c also reported poorer emotional well-being and quality of life (Puri et al., 2013). Indeed, psychological distress is very common among children and adolescents with T1D, and research consistently finds that youth with long-term illnesses such as diabetes are more likely to experience mental health symptoms compared to the general population (Jaser, 2010). A large cross-sectional survey of 2,394 German adolescents with T1D found that nearly one-third screened positive for anxiety or depression, rates higher than typically observed in the general adolescent population (Reinauer et al., 2023). A systematic review and meta-analysis further confirmed this pattern, estimating pooled prevalence rates of ~30% for depressive symptoms and ~32% for anxiety symptoms among youth with T1D (Buchberger et al., 2016). Furthermore, a large cohort study of 2,672 youth (aged 10-21 years) found that higher mean HbA1c was significantly associated with

greater depressive symptomology (Lawrence et al., 2006). These poor psychological outcomes can be lasting, with a medium-sized (N = 110) longitudinal study finding that 12-years post-diagnosis, those with T1D, compared to non-diabetic peers, were more likely to be referred for mental health treatment, suggesting that T1D can have long lasting effects on emotional outcomes over time (Northam et al., 2010)

Alongside depression and anxiety, these patients are particularly susceptible to unique psychological stressors known as fear of hypoglycemia and diabetes distress, two of the most studied diabetes-specific psychological outcomes. Given the danger of hypoglycemia, it is expected and even adaptive for patients and their families to worry about this consequence. However, recurrent hypoglycemia (which predicts fear) can lead to significant anxiety, disruptions in daily activities, suboptimal diabetes management and glycemic control (Driscoll et al., 2016). In an observational study of 24 young children with type 1 diabetes, parents who reported greater fear of hypoglycemia kept their child's blood glucose higher on average, leading to poorer glycemic control (Patton et al., 2007). Likewise, a prospective repeated-measures study of 35 young adults found that higher fear of hypoglycemia was associated with maladaptive self-care behaviors, including increased caloric intake and reduced physical activity, which contributed to greater glycemic variability (Martyn-Nemeth et al., 2017). Thus, fear of hypoglycemia is a strong predictor for suboptimal diabetes management.

Diabetes distress is another commonly studied psychological outcome associated with T1D, and research suggests it affects more than half of adolescents with T1D (Hedge et al., 2023). Diabetes distress is an umbrella term that includes the feelings of frustration, defeat, and overwhelm caused by the ever-present demands of managing T1D. These feelings may lead to pessimism and lower self-efficacy, which can cause patients to become less adherent to their

treatment regimen, and is associated with worsened glycemic control (Rodríguez-Muñoz et al., 2024). While fear of hypoglycemia and diabetes distress have strong overlap with other mental health disorders, they warrant specific approaches and interventions. In support of this position, research has found that diabetes distress mediates the association between poor glycemic control and depression (van Bastelaar et al., 2010). Assessing and addressing diabetes distress and fear of hypoglycemia is therefore a critical treatment goal for youth with T1D. These findings suggest that psychological intervention can improve not only mental health, but also treatment adherence and glycemic outcomes among patients who struggle with the burden of this chronic illness.

1.8 Behavioral Health Intervention in Pediatric Type 1 Diabetes

Pediatric psychology is an interdisciplinary field that aims to meet the behavioral, developmental, and psychological needs of children, adolescents, and families within healthcare settings. Specifically, this field focuses on improving health and self-care behaviors while treating the emotional effects of medical conditions in young patients and their families. Integrated behavioral health teams regularly utilize pediatric psychologists in their practice to address topics such as psychosocial development, mental health, self-care behaviors, and family functioning as they relate to health outcomes. Among youth with T1D, interventions often focus on teaching behavioral strategies for improved glycemic control and cognitive strategies for improved psychological well-being.

Psychological interventions can target numerous behavioral and emotional factors that are highly relevant to optimizing glycemic control. Interventions for this population are often rooted in either cognitive behavioral therapy (CBT) or behavioral family systems therapy (BFST) strategies and aim to improve patients' adjustment to and management of this chronic medical condition (Martire & Schulz, 2007). Therapeutic targets can be variable and should be patient

specific. However, common targets of these therapies include behavior change and emotional regulation skills (in the case of CBT), and problem-solving and communication skills (in the case of BFST). Helping families identify and resolve issues as well as set goals is a common theme across all treatment methods for diabetes-specific pediatric psychologists. CBT has historically been the choice intervention modality in this population. With its robust evidence base and positive outcomes, a systematic review concluded that CBT is the most extensively researched form of psychotherapy, with no other approach demonstrating systematic superiority, citing it as the "gold standard" in psychotherapy (David et al., 2018). Behavioral family systems therapy for diabetes (BFST-D) has also garnered strong evidence in its ability to treat family conflict, improve communication and enhance problem-solving skills. One medium-sized RCT (N = 104) of BFST-D found that this intervention significantly improved family conflict and treatment adherence compared to two control groups (standard care and an emotional support group). These finding were especially true in patients with clinically concerning baseline HbA1c values (Wysocki et al., 2006). In general, the majority of behavioral/psychosocial interventions in diabetes focuses on self-care issues (regiment acceptance) and emotional issues (diabetes distress) (Peyrot & Rubin, 2007; Rechenberg & Koerner, 2021)

Numerous randomized controlled trials (RCTs) studying psychological interventions for improving outcomes for pediatric T1D exist, though interestingly, results of these studies are incongruent. A systematic review by Winkley et al. (2006) summarized the findings of ten RCTs and found that the glycated hemoglobin of children decreased on average by 0.48% following psychological treatment. However, this meta-analysis also found that the existing RCTs at the time had moderate to poor quality as measured by selection bias, attrition bias, and detection bias and relatively small sample sizes (8 studies with less than 100 participants). Thus, these authors

concluded that support for the role of psychological intervention in improving HbA1c outcomes was weak but clinically significant. A follow-up review by the same authors analyzed 20 RCTs from 2003-2016 focused on pediatric populations with T1D and concluded that psychological interventions did not significantly enhance glycemic control (Winkley et al., 2020). These discrepant findings were interpreted in multiple ways.

Primarily, this seminal 2020 metanalytic review found that the evidence from the selected studies was rated as being of much higher quality, and therefore more likely to contain reliable estimates. Second, these authors also noted that there was an increased use of attention control groups in their follow-up review, potentially bridging the gap between the outcomes of patients with and without behavioral health intervention. Finally, this revised review also found significant heterogeneity between studies and type of provider delivering behavioral health intervention (diabetes specialists vs. pediatric psychologists). Despite this heterogeneity, they did not find statistically significant differences in efficacy of interventions delivered by psychology professionals versus diabetes specialists. Thus, while psychological and diabetes specialist interventions appear comparable overall, understanding the unique mechanisms and contributions of pediatric psychologists remains an important next step in advancing diabetes care.

Decades of research underscore the importance of self-care behaviors in achieving optimal glycemic control. Psychological interventions have proven effective in enhancing motivation, self-efficacy, while also reducing stress, anxiety, and burnout (factors known to contribute to poorer outcomes). Cognitive and behavioral strategies that challenge negative thoughts and foster motivation are thought to play a central role in improving glycemic control. Indeed, numerous randomized controlled trials have demonstrated both clinically and statistically

significant reductions in HbA1c following psychological interventions. However, recent meta-analyses highlight persistent variability in findings and emphasize the need for further research to determine which approaches most effectively impact glycemic outcomes. One emerging question concerns the specific contribution of diabetes-focused psychologists. Investigating outcomes in real-world clinical settings, where behavioral health interventions are integrated into standard medical care and delivered by pediatric psychologists to patients with suboptimal glycemic control, may clarify the unique value these providers bring to diabetes care teams.

1.9 Theoretical Model

Theories concerning health behavior and behavior change are comprehensive. These models include the Behavioral Model (Peyrot & McMurry, 1985), the Health Belief Model (Janz & Becker, 1984), Operant Learning Theory (Skinner, 1938), the Transtheoretical Model (Prochaska & DiClemente, 1983), Social Cognitive Theory (Bandura, 1986), and the Self-Regulation Theory (Carver & Scheier, 1998). Intervention and treatment modalities for health and self-care behaviors among individuals with chronic illnesses should be grounded in one or more of these theoretical models. While providers may utilize any number of these theories in their treatment approach, two core issues related to T1D management have been identified in research. These themes are: 1) self-care issues that relate to treatment acceptance and adherence and 2) psychological issues such as diabetes distress and depression (Peyrot & Rubin, 2007). Meta-analyses have found that improving problem-focused coping (strategies to resolve and/or prevent problems) and emotion-focused coping (strategies to manage one's internal state when immediate resolutions are not available) have been associated with more positive diabetes related health outcomes (Peyrot & Rubin, 2007).

The bidirectional relationship between psychological burden and diabetes-related clinical outcomes has also been supported in numerous studies. As noted, T1D is associated with higher risk for anxiety and depressive symptoms, and these symptoms often interfere with the self-care behaviors necessary for optimal diabetes health outcomes (Hedge et al., 2023). In response to these and similar findings, the American Association for Diabetes Education (AADE) proposed seven key self-care behaviors (ADCSE7) for effective management and improved clinical outcome measures in T1D (Kolb, 2021). See Figure 1 for a graphic representation of the ADCSE7 behaviors. These factors include problem solving, reducing risks, monitoring, healthy eating, remaining active, and healthy coping. This framework is rooted in research that emphasizes the importance of psychological and behavioral support managing diabetes. Pediatric psychologists and integrated behavioral health teams can address these core issues by attending to the ADCSE7.

The present study proposes an integrated theoretical framework grounded in cognitive-behavioral intervention that targets the diabetes self-care behaviors proposed in the ADCSE7. This framework (Figure 2) proposes that cognitive-behavioral intervention strategies can address and improve patients' abilities to abide by the ADCSE7 self-care behaviors. In addition to addressing behavioral factors associated with improved diabetes outcomes, this model highlights the ways in which cognitive-behavioral interventions can address the key predictor of glycemic control proposed by the ADCSE7 – healthy coping. Psychological influences and the behaviors necessary for managing T1D must be considered when treatment teams aim to improve patient outcomes. Studying health outcomes associated with diabetes through this integrated lens will result in data that can be used to support both the ADCSE7 and behavioral health intervention as methods for improving health outcomes, and lead to improved interventions for this population.

1.10 Significance and Aims

Despite decades of research into the epidemiology, pathology, diagnosis, and treatment of T1D, much of the evidence supporting psychological and behavioral interventions for improving glycemic outcomes comes from highly controlled randomized clinical trials (Hood et al., 2010). Some meta-analytic reviews of these trials have demonstrated that psychological interventions can produce clinically and statistically significant improvements in HbA1c, suggesting that such approaches can enhance self-management and glycemic control. However, these same reviews also note important limitations. Namely, that findings are often derived from research conducted under tightly controlled experimental conditions, which may limit generalizability to typical clinical settings. Moreover, heterogeneity across studies, including differences in intervention type and provider background (e.g., diabetes specialists versus psychologists), continues to challenge the field's understanding of which factors drive the greatest benefit.

To address these gaps, recent research has begun to examine the real-world effectiveness of behavioral health interventions integrated into standard diabetes care. For instance, Galler et al. (2020) found that children and adolescents receiving psychological care in a routine clinical setting maintained stable HbA1c levels over time, whereas those not receiving such care experienced worsening glycemic control. Building on this work, the present study utilizes a retrospective cohort design to evaluate the association between behavioral health intervention and HbA1c outcomes among pediatric and young adult patients with T1D receiving routine diabetes care. This approach allows for the evaluation of behavioral health effectiveness over time in a regional, multidisciplinary care context thereby complementing and extending the insights gained from prior controlled trials. Specifically, the aims of this study are: (1) to evaluate the association between receiving behavioral health intervention and HbA1c outcomes,

and (2) to determine whether the dose of behavioral health intervention, defined as the number of visits with a pediatric psychologist, is associated with glycemic outcomes.

Chapter 2: Methods

2.1 Overview and Study Design

The current study aims to characterize the association between behavioral health intervention and HbA1c among pediatric and young adult patients with T1D. Participants in this study were patients seen in Oregon Health & Science University's Harold Schnitzer Diabetes Health Center (HSDHC) in Portland, Oregon from 2008 to 2023. Longitudinal electronic health record (EHR) data were extracted from Oregon Health & Science University's (OHSU's) medical record system. EHR data included patient medical record number, date of birth, sex assigned at birth, race, ethnicity, visit type, visit date, provider type, provider specialty, and HbA1c lab results. This study was approved by the OHSU IRB (FWA #18379).

This sample comprises patients who received ongoing diabetes care at the HSDHC. The standard of care for treatment initiation at the HSDHC includes an initial referral to a pediatric psychologist for evaluation, psychosocial consultation, and behavioral health education. Patients are also scheduled for routine, ongoing medical care through the HSDHC on a schedule of every three to four months. During these follow-up care visits, patients who exhibited suboptimal diabetes self-management were referred to pediatric psychologists for recommendations and brief intervention as co-occurring care. Follow-up care was provided as clinically indicated.

2.2 Inclusion Criteria and Time Point Selection

The cohort of the current study includes only patients who were seen by a pediatric psychologist for follow-up intervention. Those who received only a consultation visit at the initiation of care in the HSDHC were not included. This inclusion criterion was established to account for two key factors. First, at the time of initial psychological consultation, patients' HbA1c levels are expected to be out of range as a result of being newly diagnosed with T1D.

Therefore, the HbA1c levels associated with this time would not be considered an accurate measurement of glycemic control during treatment, given expected improvements due to standard medical care. Second, the standard of care in the HSDHC is to not provide behavioral intervention until a patient exhibits need for such a referral. Thus, patients in the current study must have met with a diabetes-specific psychologist at least twice to meet criteria for engaging in psychological intervention (i.e., initial consultation plus a minimum of one follow-up appointment).

Patient participants for this study met the following inclusion criteria: (1) had a diagnosis of T1D, 2) were between 0 and 25 years of age at the time of intervention initiation, (3) had seen a diabetes-specific psychologist at least twice, and (4) had at least two HbA1c values within the appropriate time frame, described below.

2.3 Measures

Psychological Encounters

Psychological encounters within the HSDHC were determined using a filter criterion which referenced visit type and provider specialty concurrently to ensure encounters were unique visits with diabetes-specific psychologists. Further confirmation of the accuracy of psychological encounters cross-referenced the name of the provider with their license and position within the HSDHC.

HbA1c

HbA1c is a weighted average of blood glucose levels during the preceding 90 days. This value is reported in percentages which refer to the proportion of a patient's blood hemoglobin protein that has glucose attached to it. A higher percentage correlates to a higher average blood glucose level. Among patients with diabetes, a common treatment goal is to maintain an HbA1c

level below 7.5%, though below 8.0% is considered a clinically acceptable target. Importantly, older assays for HbA1c have traditionally limited the upper bound of this test to >14%. However, newer assays are able to detect any level of HbA1c. A small portion (N = 20) of the cohort had HbA1c values described as "Null" or " >14%" in their medical record. Due to the imprecise nature of these values, these patients were not included in the final sample.

Baseline HbA1c. Patients' baseline HbA1c value was defined as an HbA1c value that was between 0 to 90 days prior to the date of intervention initiation (i.e., the first follow-up visits after the initial psychological consultation), which we defined as the index date. If a patient had more than one HbA1c value in the 90 days prior to the index date, the HbA1c value most proximal to the index date was treated as the baseline HbA1c.

Follow-up HbA1c. Follow-up HbA1c values were defined as any assay conducted greater than 90 days following the index date. This was to ensure that post-intervention HbA1c readings did not include blood glucose in the pre-intervention period, as HbA1c measures average blood glucose in the past 90 days. Patients who did not have an HbA1c value greater than 90 days following their index date were excluded. To capture all possible changes associated with treatment, the current study analyzed all eligible HbA1c values that occurred between 90 days and one year following the index date.

Covariates for Aim 1 and 2

Covariates for this study included number of endocrinology encounters over the 12 months following the index date and a binary variable of utilization of CGM prior to or during the 12-month post-intervention follow-up window. Henceforth, these two covariates are described as "healthcare utilization". Additionally, as research suggests that demographic

characteristics of sex and age are associated with differing levels of glycemic control and overall health outcomes, these variables were also included as covariates (Bryden et al., 2001)

2.4 Aims and Analytic Plan

All statistical analyses were run using R version 4.1.0 (R Core Team, 2024). Descriptive statistics characterized demographic variables of sex assigned at birth, race, ethnicity, and age at intervention initiation. Additional descriptive statistics characterized CGM usage, number of endocrinology encounters associated with T1D treatment during the 12-month window, and in- vs. out-of-range baseline HbA1c (defined as less than 8.0% for in-range and 8.0% or above for out-of-range). Participants' missing demographic data were labeled as "unknown". These participants with missing demographic data were included in the primary analyses. There were no analyses conducted to describe missing demographic HbA1c values in the follow-up windows.

Aim 1: Quantify changes in HbA1c levels following behavioral health intervention among pediatric and young adult patients with T1D.

Hypothesis 1. Patients will evidence statistically significant reductions in HbA1c following initiation of behavioral health intervention after controlling for healthcare utilization variables, assigned sex at birth, and age at baseline.

Aim 1 Analytic Plan. The primary focus of Aim 1 was to assess changes in patients' HbA1c levels from pre- to post-psychological treatment. To accomplish this aim, a series of linear mixed-effects regression models were conducted using longitudinal HbA1c values as the outcome, including linear, quadratic, and cubic trends across time. The model included a fixed effect for each polynomial term to estimate the average trajectory of HbA1c values from baseline to one year following intervention. Fixed effects were also added to control for assigned sex at

birth, age at treatment initiation, and healthcare utilization. A random intercept term was included to account for individual differences in baseline HbA1c.

Aim 2*:* Determine the association between number of encounters with a pediatric psychologist and changes in HbA1c levels for 12 months following the initiation of treatment.

Hypothesis 2. Greater number of visits with a pediatric psychologist will be associated with greater reductions in HbA1c treatment after controlling for healthcare utilization, assigned sex at birth, and age at baseline.

Analytic Plan 2. Aim 2 was tested by adding a predictor for total number of encounters (time invariant) and an interaction between time and number of encounters to the mixed-effects regression models in Aim 1 described above.

Statistical Power

A clinically change difference in HbA1c values was defined as a change of ≥5 mmol/mol (0.5%), a standard that has been set by the National Institute for Health and Care Excellence (NICE) guidelines and used in prior literature. Meta-analyses of behavioral interventions for pediatric patients with T1D have also shown consistent changes in HbA1c of between 0.4% and 0.5% following intervention (Winkley et al., 2006). The current study therefore defined clinically significant changes in HbA1c as any change greater than or equal to 0.5%. The equivalent effect size was determined by the taking this clinically significant change and dividing it by the standard deviation of the baseline HbA1c values. This resulted in a Cohen's d value of 0.20. The required sample size was estimated using an alpha of 0.05 and a power of 0.80. For Aim 1, assuming $\alpha = 0.05$, power = 0.80, and Cohen's d = 0.20, a minimum of N = 198 was determined to be required to detect a clinically significant effect. The current study's fixed sample size of N = 314 exceeded the minimum necessary sample size. We did not compute a priori sample size

needed for Aim 2 as it was primarily an exploratory analysis of the association of intervention dose and HbA1c trajectory.

Chapter 3: Results

3.1 Descriptive Results

Between 2008 and 2023, the HSDHC treated 2,524 unique patients. Of these, 854 patients were seen by a diabetes-specific psychologist for intervention following the initial consultation. 766 of these patients had HbA1c values collected at OHSU and 314 of these patients had HbA1c values within the windows defined. See the study flow chart in Figure 3. Patient age at the time of treatment initiation ranged from 1.2 to 24.9 years (Mean = 13.1, Median = 13.2, SD = 5.1). 20 patients (6.4%) were under 5 years old, while 51 (16.2%) were over 18 years old at treatment initiation. 144 patients (45.9%) identified as female, 250 patients (79.6%) identified as White, and 41 (13.1%) patients identified as a racial minority. N = 87 included an ethnic identity in their medical record. N = 70 of these patients identified as non-Hispanic. Ethnic identity descriptive results were limited by 227 (72.3%) unknown values. 52 patients reported a White non-Hispanic identity, and 35 patients reported identifying as a racial/ethnic minority (defined as non-white race and/or Hispanic/Latino). See Table 3.

The percentage of patients in the sample whose baseline HbA1c was clinically elevated (greater than or equal to 8.0%) was 66.2% (N=208), while 33.8% (N=106) had clinically acceptable baseline HbA1c values. Among the clinically elevated sub-sample, mean HbA1c was 10.74% (SD = 2.19%). Among the clinically in-range sub-sample, mean HbA1c was 6.98% (SD = 0.79%). See Figure 4 for a graphic depiction of baseline HbA1c values.

3.2 Healthcare Utilization

The average number of encounters with a pediatric psychologist during the 12-month window was 2.8 (Range = 2-48, SD = 4.7, Mode = 2). The average number of endocrinology

encounters during the 12-month window was 3.52 (Range = 0-10, SD = 2.02). Ninety-five patients (30.3%) were utilizing a continuous glucose monitor before or during the 12-month window. The 314 patients in the sample had a total of 2,071 unique visits within the HSDHC. These included 1104 (53.3%) endocrinology visits and 820 (39.6%) psychology visits. See Figure 5 for a graphic depiction of the distribution of psychology visit encounter numbers. Of note, all outpatient visits included in this count occurred within the diabetes health center only; therefore, this count does not capture total healthcare utilization within the 12-month window. Counts of outpatient visits within the larger OHSU, Doernbecher Children's Hospital, and community outpatient systems were not obtained.

3.3 Aim 1: Analytic results - Examining change in HbA1c values over time

Across participants, mean baseline HbA1C was 9.47% (Range = 4.6-18.4%, SD = 2.56%). To determine the best-fitting model of HbA1c change over time, linear, quadratic, and cubic polynomial mixed-effects models were compared using the Bayesian Information Criterion (BIC). The cubic model demonstrated the best fit (BIC = 3608.64), compared to the quadratic (BIC = 3611.99) and linear models (BIC = 3630.08). These findings suggested that a cubic trajectory best captured changes in HbA1c over time. As shown in Figure 6, the cubic model depicted an initial, rapid improvement in HbA1c following psychological intervention. This model also revealed that, over time, HbA1c values tended to increase slightly, beginning on or around month 5, and subsequently decrease slightly around month 10, $\beta = -0.004$, SE = 0.001, $t = -3.29$, 95% CI [-0.002. -0.001], $p = .001$ These results confirmed a non-linear trajectory of HbA1c over time. See Table 4 for results of Aim 1 with the cubic term. In the full sample, N = 132 patients (42%) evidenced a clinically significant decrease (greater than or equal to 0.5%) in HbA1c from baseline to last available lab value.

3.4 Aim 1: Sensitivity Analyses

Sensitivity analyses assessed differences in the effects of psychological intervention on HbA1c among the subsample of patients with clinically elevated HbA1c levels at baseline. As shown in Table 5, of the 208 patients whose baseline HbA1c was equal to or above 8.0%, N = 115 (55.3%) had a clinically significant decrease in HbA1c, compared to N = 17 (5.4%) of patients with HbA1c less than 8.0% at baseline.

In this sensitivity analysis, the cubic model demonstrated the best fit (BIC = 3608.64), compared to the quadratic (BIC = 3610.99) and linear models (BIC = 3630.08). These findings suggest that a cubic trajectory best captures changes in HbA1c over time among individuals with a clinically elevated baseline HbA1c. As shown in Figure 7, findings again demonstrated an initial, rapid improvement in HbA1c following psychological intervention. This model also revealed that, over time, HbA1c values tended to increase slightly and subsequently decrease slightly, near the 5- and 10-month marks, respectively, $\beta = -0.004$, SE = 0.001, $t = -2.89$, 95% CI [−0.007, −0.001], p = .004. See Table 6.

3.5 Aim 2: Analytic Results - Examining the association of number of psychological encounters with HbA1c

To examine whether the number of psychological encounters was associated with the rate of change in HbA1c values, Aim 2 utilized a model that included an interaction between number of psychological visits and time. As Aim 1 indicated that a cubic time term provided the best fit for HbA1c trajectories, this polynomial was retained in Aim 2. The results of this interaction effect model revealed that, while HbA1c levels tended to decrease over time, the interaction between psychological visits and cubic time was not significant, $\beta = 0.00002$, SE = 0.00026, t =

0.06, 95% CI [-0.001, - 0.001], p = .952, indicating no differential trajectory in HbA1c based on number of psychological encounters. See Table 7.

3.6 Aim 2: Sensitivity Analyses

In the first sensitivity analysis for Aim 2, baseline HbA1c was used as a binary variable to detect the effect of behavioral health intervention on patients with in-range (HbA1c equaling less than 8.0%) versus out-of-range (HbA1c greater than or equal to 8.0%) glycemic control in certain aims. As with Aim 1, this model was re-run with only the sub-sample of patients who had clinically elevated HbA1c values at baseline (N=208). In this model, the interaction effect was also not significant, β = -0.00016, SE = 0.00038, t = -0.42, p = .67. This suggests that the rate of HbA1c change over time did not differ based on the number of psychological visits in the clinically elevated subsample. See Table 8.

3.7 Additional Sensitivity Analysis

Due to the wide array of psychological encounters within the sample (Range: 2 – 47), a sensitivity analysis examining the interaction of cubic time and dose of psychological intervention on HbA1c utilizing groups of encounters was run. The mode of psychological encounters within the sample was 2. The groups of encounters included in this sensitivity analysis were: 1) 2 visits, 2) 3 visits, 2) 4+ visits. These groups contained N = 216 (68.8%) patients in the 2-visits bin, N = 35 (11.1%) patients in the 3-visits bin, and N = 63 (20.1%) patients in the 4+ visits bin. See Figure 8.

A linear mixed-effects regression model was used to evaluate the association between psychological visit number (2, 3, or 4+), time (modeled cubically), and their interaction on HbA1c levels. Sex assigned at birth, healthcare utilization variables, age, and a binary baseline HbA1c status (in-range or clinically elevated) were used as covariates. While not statistically

significant, having three visits was associated with steeper initial declines in HbA1c over time as compared to having exactly two psychological visits (see Figure 9). Despite this, there was no significant interaction between time (modeled cubically) and those with exactly three or four or more psychological visits, suggesting that the trajectory of HbA1c over time for these individuals was not significantly different from those with exactly two psychological visits. See Table 9.

Chapter 4: Discussion

The global incidence of T1D has doubled over the past two decades, with no curative therapies currently available (Battaglia et al., 2015). Despite treatment methods that theoretically promise stable and positive health outcomes, only a minority of youth with T1D achieve adequate glucose control, the absence of which can result in morbidity, diminished quality of life, and in extreme instances, death. Additionally, it is well-documented that glycemic control is prone to deterioration during adolescence (Bitsko et al., 2013; Harris et al., 2014). As effective treatment and monitoring options exist, access to treatment and poor treatment adherence is thought to explain the current dearth of proper glucose regulation among those with T1D. Adequate self-care behaviors as one of the primary barriers to optimal diabetes outcomes suggests that behavioral and psychological interventions have significant promise for improving health outcomes among this population. However, evidence of the efficacy or inefficacy of these interventions comes predominantly from highly controlled clinical trials, while meta-analytic reviews of prior research has been inconclusive. This important study expanded upon previous work by investigating the benefit of diabetes-specific psychological intervention in a clinical care setting utilizing retrospective data.

4.10 Aim 1: Psychological intervention and HbA1c

Consistent with our hypothesis, receipt of any behavioral health intervention was associated with improved HbA1c outcomes from pre-intervention to follow-up periods. This was true while controlling for age at intervention initiation, sex assigned at birth, concurrent continuous glucose monitor use, and quantity of endocrinological care. Trends in HbA1c were best described with a cubic model. The cubic model indicated a steep, initial decline in HbA1c values following intervention, with a subsequent slight increase and decrease slightly, near the 5-

and 10-month marks, respectively. Several studies have found that behavioral interventions demonstrate efficacy at improving diabetes self-management practices and health outcomes in pediatric and young adult patients with T1D. Many of these therapies (among the most well-studied are CBT and BFST-D) are based in behavioral- and system-level theoretical models and aim to improve cognitive and behavioral coping strategies or address family conflict, communication, and problem solving (Harris et al., 2009; Wysocki et al., 2008). The majority of studies on these behavioral interventions have supported the important role of psychotherapy in this population, though some have not (Wysocki et al., 2001).

This study may provide insight into the variable evidence of the efficacy or inefficacy of behavioral health intervention within prior research. The current study identified a potential, immediate benefit of behavioral health intervention through the use of a polynomic model. In particular, patients in the current sample showcased an initial steep decline in HbA1c values collected between three and 12 months following intervention. These data provide additional support for brief intervention models. In prior research, one-year follow-up HbA1c values are among the most commonly utilized time-point for evaluating the effect of psychological intervention in pediatric populations. However, singular research studies that explore differences in immediate versus long-term outcomes are less common. Future studies that examine courses of (and gaps in) psychotherapy within follow-up periods may improve the understanding of how psychotherapy is or is not directly related to glycemic control.

Also consistent with our hypothesis, among the subsample of patients whose baseline HbA1c was clinically elevated (above 8.0%), HbA1c trajectories were also significantly associated with behavioral health intervention. As with the full sample, these trajectories were modeled best with a cubic trajectory. This is consistent with prior work finding that those with

poorer glycemic control prior to intervention respond as well or significantly greater than those with adequate glycemic control (Luo et al., 2018; Wysocki et al., 2008).

4.20 Aim 2: Quantity of psychological intervention and HbA1c

Contrary to our hypothesis, the number of psychological intervention sessions received was not significantly associated with HbA1c trajectories. This was true while controlling for age at intervention initiation, sex assigned at birth, healthcare variables, as well as baseline HbA1c values. As with the full sample, the number of psychological interventions received was not significantly associated with HbA1c trajectories in the clinically elevated sub-sample.

4.21 Aim 2: Binned psychological encounter number

Post-hoc sensitivity analyses also included a variable for grouped psychological encounters. These groups included: two visits (minimum necessary to be considered eligible), three visits, and four or more visits. Interaction terms between psychological visits number (grouped) and time modeled cubically were all non-statistically significant. Although not statistically significant, there was a clinically significant pattern of change in HbA1c in the group of patients who received three visits versus two and four or more visits. Specifically, in the initial follow-up period, those in the three visit bin had clinically lower HbA1c values than their counterparts. Interestingly, this relationship was inverse in the 12-month follow-up, wherein those with two and four or more visits had clinically lower HbA1c values than the 3 visit group. Although these findings were not statistically significant, differences of greater than 0.5% in HbA1c are relevant for long term complications. Visualizing these differences also highlights the importance of larger and more equal subgroups, as the smaller sample size of patients in the three visit group may have impacted the ability to detect statistically significant differences between groups. Additionally, while this trend does not imply causality (i.e., that having exactly

three visits results in a different trajectory of HbA1c), it may reflect unique characteristics of this subgroup. Given that intervention techniques did not differ for patients who received only three visits, the observed pattern could indicate that individuals who attend three visits and then discontinue treatment differ meaningfully from those who complete more or fewer sessions. Notably, patients with exactly two visits did not exhibit as steep an increase (otherwise defined as a rebound) in HbA1c over time. Qualitative analysis of the subgroup of patients who attended exactly three psychological visits may help identify factors contributing to early dropout and inform strategies to improve retention among patients at higher risk of discontinuing care. Further, the group of patients who experienced only three visits was notably smaller than the two other groups (N = 35 as compared to N = 216 and N = 63 for the two visits and four or more visits' groups, respectively). Thus, future studies interested in informing strategies for treatment retention should expand upon this work with a larger sample size.

4.3 Limitations and future directions

It is important to consider study results in the context of several limitations. First, the current sample includes patients spanning a broad age range, reflecting markedly different developmental stages. Thus, intervention strategies are likely to vary widely with the age of patient. For example, for younger patients, interventions are more likely to be family-focused versus individual. This is just one example of many differences in treatment approaches inherent in the age of a patient. The differences inherent in these age-appropriate strategies might affect this study's results. Furthermore, aggregating HbA1c trajectory data across age groups undermines the important variable that is changes in hormone (insulin) sensitivity throughout development. As noted, adolescence is a period of time in which HbA1c can vary widely

independent of adequate self-care behaviors. Thus, the effectiveness of treatment could be related more towards organ maturation than behavioral intervention in certain age groups.

Second, a central consideration in prior research on this population has been disease duration. Glycemic control tends to fluctuate considerably immediately after diagnosis, as HbA1c levels respond to the initiation of insulin therapy. In one large, multinational study of 7,606 individuals with T1D across 39 countries, HbA1c was highest at diagnosis, declined to its lowest point around 4–5 months later, and then rose steadily over the following 18 months (Prahalad et al., 2022). Although disease duration was not directly examined in the present study, it is important to note that HbA1c trajectories typically shift throughout the early years after onset. This is especially important to capitalize upon, as a recent retrospective study of 4,525 individuals with T1D found that glycemic control generally stabilizes into a long-term trajectory within the first five years post-diagnosis (Nirantharakumar et al., 2018). Thus, while the current sample likely included individuals relatively early in their disease course, prior findings underscore the value of continuing to investigate behavioral health interventions during the initial stages of treatment.

Additionally, although race and ethnicity were reported in some medical records, there were not enough data to conduct meaningful between-group analyses. Furthermore, self-reported race and ethnicity are often proxies for other characteristics known to influence health outcomes. Social determinants of health (including race, ethnicity, access to healthcare [through rurality or lack of health insurance], and lower levels of education) are known to be associated with medical emergencies, morbidity, and mortality in T1D through multi-directional biopsychosocial influences (Luo et al., 2018; Stover-Kempers et al., 2025; Torres et al., 2025). Difficulties accessing care and remaining engaged in treatments can also limit the effectiveness of

interventions and contribute to persistently high HbA1c levels. All of these variables were unfortunately unable to be included in the current study's scope.

Results of the current study did not support an association between increased quantity of psychotherapy visits in improving HbA1c levels. However, there was a wide range of number of psychological encounters, as well as a limited number of patients in specific groups (e.g. in the three-visit bin). Future research should expand on this work with larger sample size in subgroups to investigate characteristics associated with those who remain in treatment for differing lengths of time. Understanding who remains engaged and responds well to behavioral interventions will benefit future clinical trials and intervention development. Furthermore, due to this study's design and focus, causal relationships between psychotherapy and HbA1c could not be explained. Future mixed methods studies could help to further elucidate these relationships.

4.4 Implications of this study

Psychosocial challenges and psychiatric comorbidities can significantly impair self-care behaviors and overall management of T1D, contributing to poorer glycemic control and higher rates of acute and chronic adverse medical outcomes. In recognition of these risks, international clinical guidelines emphasize the integration of psychosocial care into diabetes management for children and adolescents. Consistent with these recommendations, interventions targeting the psychosocial aspects of T1D (such as coping, motivation, and family dynamics) tend to yield better outcomes than those focused solely on specific behavioral targets like blood glucose monitoring frequency (Hood et al., 2010). Research has long supported the critical role of treatment adherence in achieving adequate glycemic control, and evidence suggests that adherence difficulties during adolescence are bidirectionally linked to poor psychological outcomes (Beran et al., 2022). Within the first six years following diagnosis, psychosocial

burden (e.g., lower diabetes-specific quality of life), child behavior problems, and family functioning have all been identified as predictors of suboptimal HbA1c (Cohen et al., 2004; Hood et al., 2014). These findings underscore the importance of addressing behavioral and psychological factors early to promote both quality of life and effective glucose regulation across the lifespan (Duke et al., 2016).

In response, integrated behavioral health models have become increasingly common in pediatric diabetes clinics nationwide, with mounting evidence supporting their effectiveness. Yet, much of the existing literature is based on highly controlled trials, leaving questions about how psychological care functions in typical clinical environments. The present study contributes to this growing area by examining the real-world impact of behavioral health intervention on glycemic outcomes among youth with T1D. Specifically, it explores how psychological care, delivered as part of multidisciplinary diabetes treatment, relates to longitudinal HbA1c trends and adherence patterns. Importantly, the study also raises new questions regarding the characteristics of patients who benefit most from psychological care and those who may be lost to follow-up. Identifying these subgroups will be essential for refining treatment models, enhancing engagement, and maximizing positive outcomes for young patients living with T1D.

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Tables

Table 1

Levels of hypoglycemia and hyperglycemia

Level	BG (mg/dL)	Implications
Hypoglycemia	< 80	Dizziness, weakness, confusion, fatigue, cognitive decline resulting in the need for treatment by another person, loss of consciousness, seizures, death
Diabetic In-Range	80 - 180	Normal cognitive and biological status
Hyperglycemia	> 180	Increased thirst, urination, headache, blurred vision, risk for DKA, poor circulation, nerve damage, organ damage

Note. Implications are not exhaustive; BG = blood glucose; DKA = diabetic ketoacidosis

Table 2

Estimated average blood glucose and associated HbA1c values

HbA1c (%)	Average BG (mg/dL)	Value Descriptor
5.0	97	In Range (or Non-Diabetic)
5.3	105	In Range (or Non-Diabetic)
5.6	114	In Range (or Non-Diabetic)
5.9	123	Diabetic In Range
6.2	131	Diabetic In Range
6.5	140	Diabetic In Range
6.8	148	Diabetic In Range
7.1	157	Diabetic In Range
7.4	166	Diabetic In Range
7.7	174	Diabetic In Range
8.0	183	Higher Than Recommended
8.3	192	Higher Than Recommended
8.6	200	Higher Than Recommended
8.9	209	Higher Than Recommended
9.2	217	Higher Than Recommended
9.5	226	Clinically Concerning
9.8	235	Clinically Concerning
10.1	243	Clinically Concerning
10.4	252	Clinically Concerning
10.7	260	Clinically Concerning
11.0	272	Clinically Concerning

Note. BG = blood glucose

Table 3

Patient characteristics (N = 314)

Characteristic	N (%)
Sex in medical record	
Female	144 (45.9%)
Male	170 (54.1%)
Race	
White	250 (79.6%)
Black/African American	9 (2.9%)
Asian	4 (1.3%)
Native American	4 (1.3%)
Native Hawaiian/Pacific Islander	3 (1.0%)
Multiracial	21 (6.7%)
Other/Unknown	23 (7.3%)
Age	
< 5 years	20 (6.4%)
5 – 18 years	243 (77.3%)
> 18 years	51 (16.2%)
Ethnicity	
Hispanic or Latino	17 (5.4%)
Non-Hispanic or Latino	70 (22.2%)
Unknown	227 (72.3%)
Racial/Ethnic Status	
White non-Hispanic	52 (16.6%)
Racial/ethnic minority	35 (11.1%)
Unknown	227 (72.3%)
Baseline HbA1c	
Below 8.0%	106 (33.8%)
Equal to or above 8.0%	208 (66.2%)

Note. Percentages may not equal 100% due to rounding

Table 4

Aim 1: Results of mixed effects regression model with cubic term

Predictor	Estimate (ß)	SE	*t*	95% CI	*p*
Intercept	7.94	0.43	18.67	[7.11 - 8.77]	< .001
Time	−0.40	0.06	−7.17	[-0.51 - -0.29]	< .001
Time²	0.07	0.02	4.40	[0.04 - 0.11]	< .001
Time³	−0.004	0.00	−3.29	[-0.006 - -0.001]	.001
Sex (Male)	0.32	0.20	1.61	[-0.07 - 0.71]	.110
Age	0.05	0.02	2.51	[0.01 - 0.09]	.013
Endocrinology Visits	0.14	0.05	2.57	[0.03 - 0.24]	.011
CGM Use	−0.54	0.21	−2.53	[-0.95 - -0.12]	.012

Note. CI = Confidence Interval, CGM = Continuous Glucose Monitor

Table 5

HbA1c changes by sample or subsample

Characteristic	Value	SD
Full Sample (N = 314)		
Mean Baseline HbA1c	9.47%	2.56%
Decrease of 0.5% or more	132 (42.0%)	
Clinically Elevated Subsample (N = 208)		
Mean Baseline HbA1c	10.74%	2.19%
Decrease of 0.5% or more	115 (55.3%)	
Clinically In-Range Subsample (N = 106)		
Mean Baseline HbA1c	6.98%	0.79%
Decrease of 0.5% or more	17 (5.4%)	

Table 6

Aim 1: Results of sensitivity analysis (clinically elevated sub-sample) with cubic term

Predictor	Estimate (ß)	SE	*t*	95% CI	*p*
Intercept	9.38	0.43	21.69	[8.54 - 10.22]	< .001
Time	−0.55	0.07	−7.79	[-0.69 - -0.42]	< .001
Time²	0.09	0.02	4.15	[0.05 - 0.13]	< .001
Time³	−0.004	0.00	−2.89	[-0.007 - -0.001]	.004
Sex (Male)	−0.05	0.20	−0.26	[-0.43 - 0.33]	.793
Age	0.08	0.02	3.55	[0.03 - 0.12]	< .001
Endocrinology Visits	−0.01	0.05	−0.16	[-0.11 - 0.09]	.875
CGM	−0.37	0.22	−1.68	[-0.80 - 0.06]	.094

Note. CI = Confidence Interval, CGM = Continuous Glucose Monitor

Table 7

Aim 2: Results of linear mixed effects model

Predictor	Estimate (ß)	SE	*t*	95% CI	*p*
Intercept	8.90	0.254	35.06	[8.41 - 9.40]	<.001
Psychological visits	-0.023	0.027	-0.83	[-0.08 - 0.03	.405
Time	-0.445	0.066	-6.70	[-0.57 - -0.32	<.001
Time²	0.076	0.02	3.89	[0.04 - 0.12]	<.001
Time³	-0.004	0.001	-2.76	[-0.01 - -0.001]	.006
Sex (Male)	0.312	0.201	1.55	[-0.08 - 0.70]	.122
Endocrinology visits	0.085	0.05	1.73	[-0.01 - 0.18]	.085
CGM	-0.534	0.215	-2.48	[-0.95 - -0.12]	.014
Psychological visits x Time	0.015	0.012	1.26	[-0.01 - 0.04]	.210
Psychological visits x Time²	-0.001	0.004	-0.38	[-0.01, 0.01]	.707
Psychological visits × Time³	0.00002	0.003	0.06	[-0.001 - 0.001]	.952

Note. CI = Confidence Interval, CGM = Continuous Glucose Monitor

Table 8

Aim 2: Sensitivity analysis (clinically elevated sub-sample)

Predictor	Estimate (ß)	SE	*t*	95% CI	*p*
Intercept	10.65	0.281	37.87	[10.11 - 11.20]	< .001
Psychological visits	0.016	0.042	0.39	[−0.07 - 0.10]	.700
Time	−0.601	0.089	−6.74	[−0.78 - −0.43]	< .001
Time²	0.084	0.027	3.16	[0.03 - 0.14]	.002
Time³	−0.0035	0.0018	−1.95	[−0.01 - ~0.00]	.052
Sex (Male)	−0.083	0.199	−0.42	[−0.47, 0.30]	.677
Endocrinology visits	−0.081	0.049	−1.66	[−0.18 0.01]	.098
CGM	−0.427	0.225	−1.89	[−0.86, 0.01]	.060
Psychological visits x Time	0.018	0.018	1.01	[−0.017, 0.053]	.314
Psychological visits x Time²	0.0005	0.006	0.10	[−0.011, 0.012]	.924
Psychological visits × Time³	−0.0002	0.0004	−0.42	[−0.001, 0.001]	.672

Note. CI = Confidence Interval, CGM = Continuous Glucose Monitor

Table 9

Aim 2: Sensitivity analysis (psychological visits binned)

Predictor	Estimate (ß)	SE	*t*	95% CI	*p*
Intercept	10.09	0.23	44.11	[9.64 - 10.53]	<.001
Psychological Visits					
2 visits	*Reference*	-	-	-	-
3 visits	-0.48	0.28	-1.71	[−1.02 - 0.06]	.088
4+ visits	0.12	0.25	0.50	[−0.36 - 0.60]	.620
Time	-0.37	0.08	-4.57	[−0.52 - −0.21]	< .001*
Time²	0.06	0.02	2.62	[0.02 - 0.10]	.009*
Time³	-0.0028	0.002	-1.90	[−0.01 - ~0.00]	.057
Sex (Male)	0.06	0.15	0.37	[−0.24 - 0.35]	.714
Endocrinology Visits	-0.001	0.04	-0.02	[−0.07 - 0.07]	.985
CGM	-0.17	0.17	-1.04	[−0.49 - 0.15]	.300
Baseline HbA1c (In-Range)	-2.51	0.17	-15.2	[−2.83 - −2.19]	< .001*
2 visits x Time	*Reference*	-	-	-	-
3 visits x Time	-0.09	0.15	-0.59	[-0.39 - 0.21]	.556
4+ visits x Time	0.05	0.12	0.43	[−0.19 - 0.29]	.666
2 visits x Time²	*Reference*	-	-	-	-
3 visits x Time²	0.03	0.05	0.71	[−0.06 - 0.120]	.479
4+ visits x Time²	-0.01	0.04	-0.18	[−0.08 - 0.06]	.854
2 visits x Time³	*Reference*	-	-	-	-
3 visits x Time³	-0.001	0.003	-0.44	[−0.01 - 0.01]	.660
4+ visits x Time³	0.0001	0.002	0.04	[−0.005 - 0.005]	.966

Figures

Figure 1

Graphic representation of the ADCES7 key self-care behaviors (Kolb, 2021)

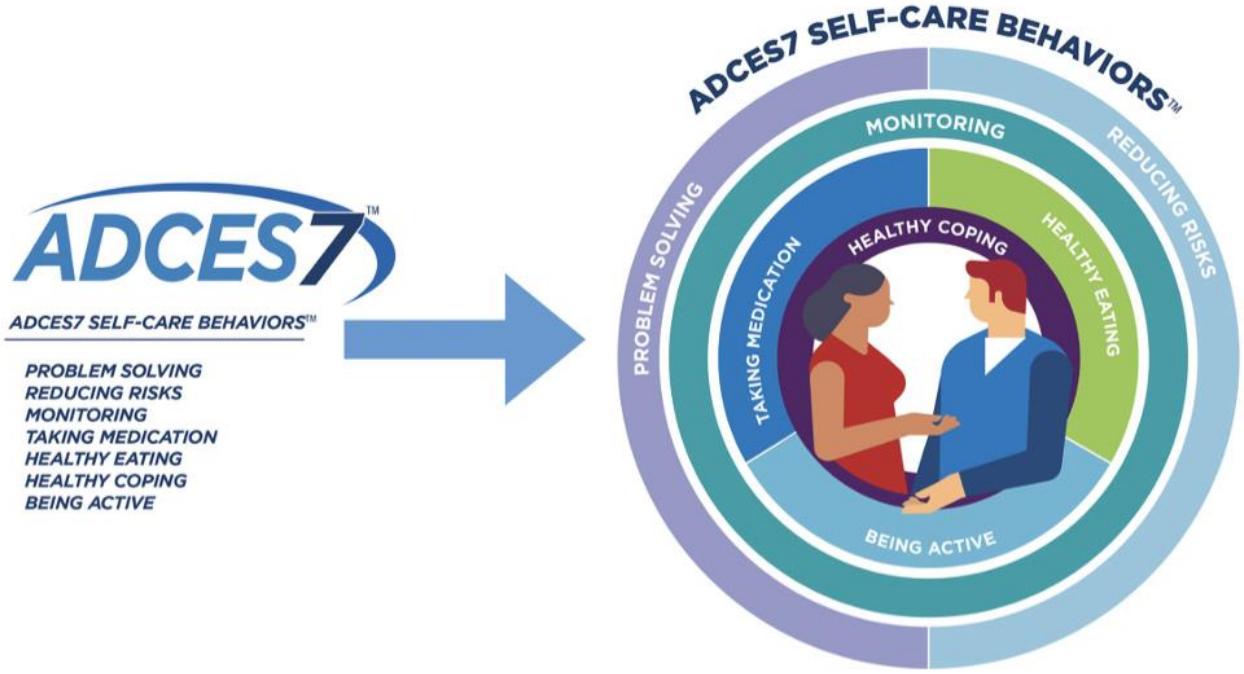


Figure 2

Theoretical Model

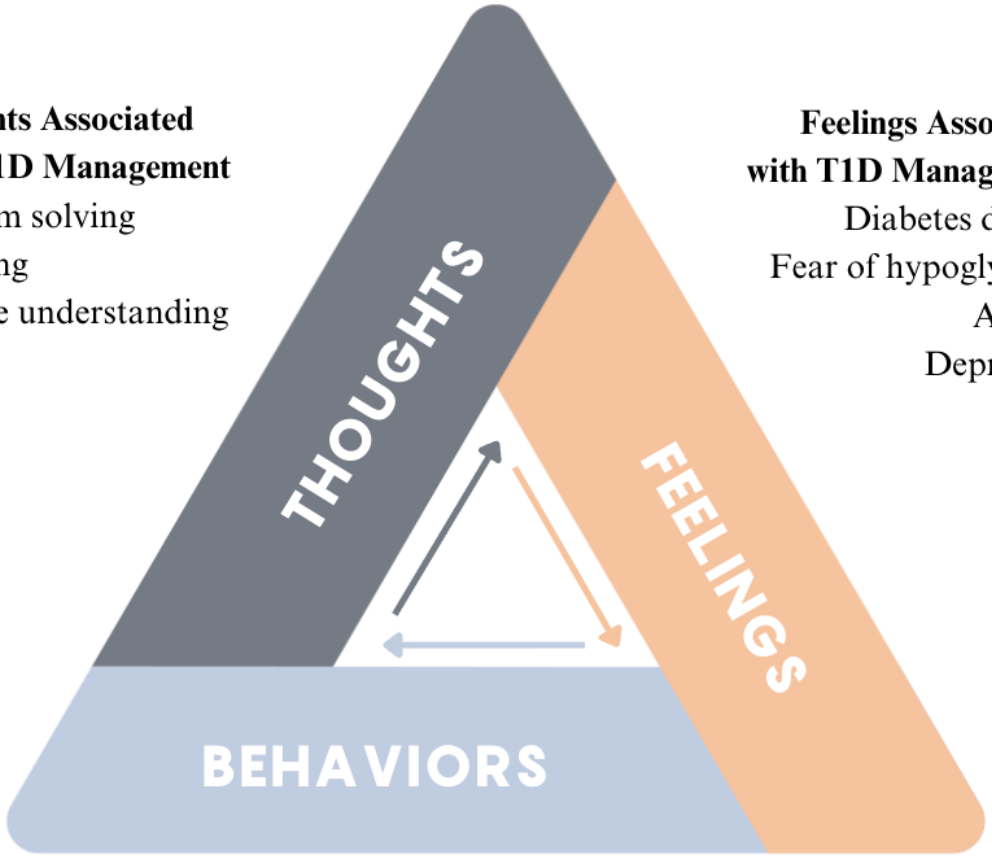


Figure 3

Study Flow Diagram

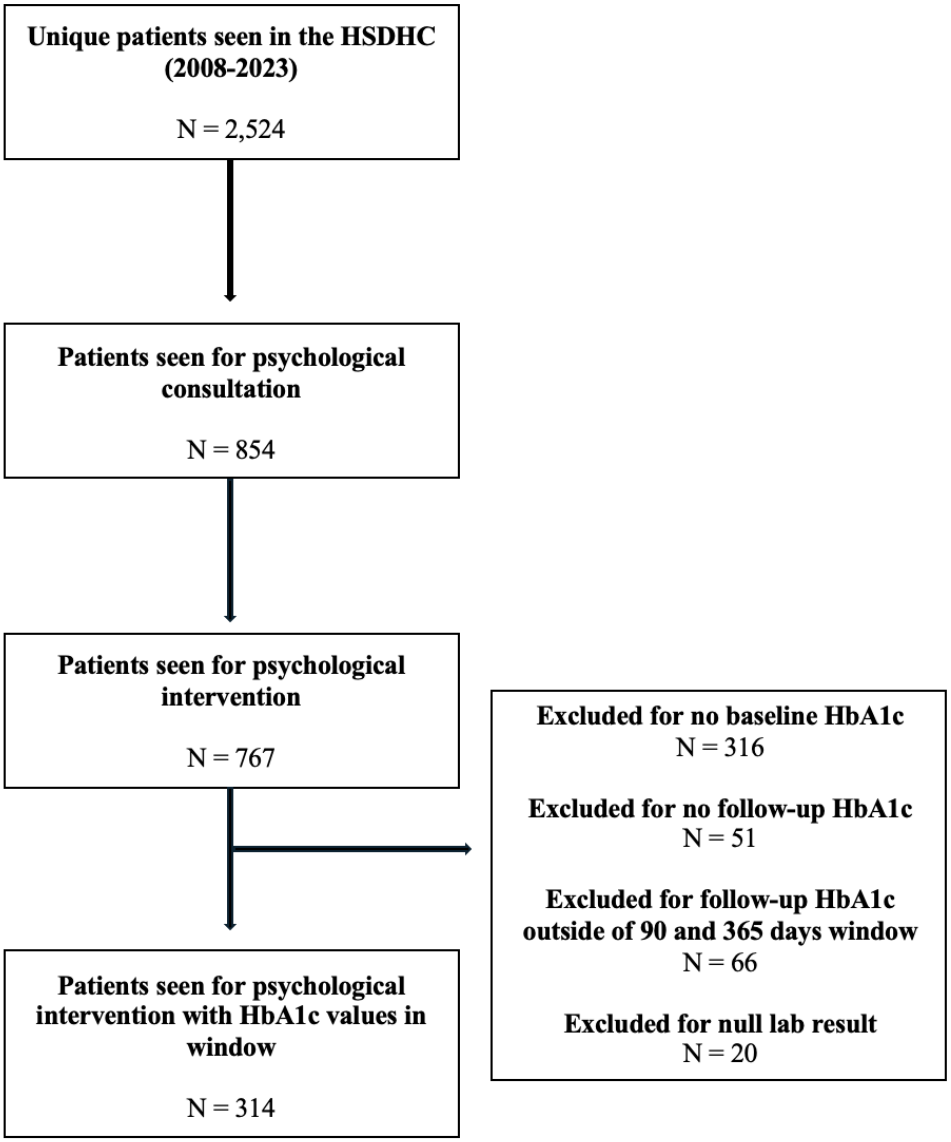


Figure 4

Distribution of Baseline HbA1c values

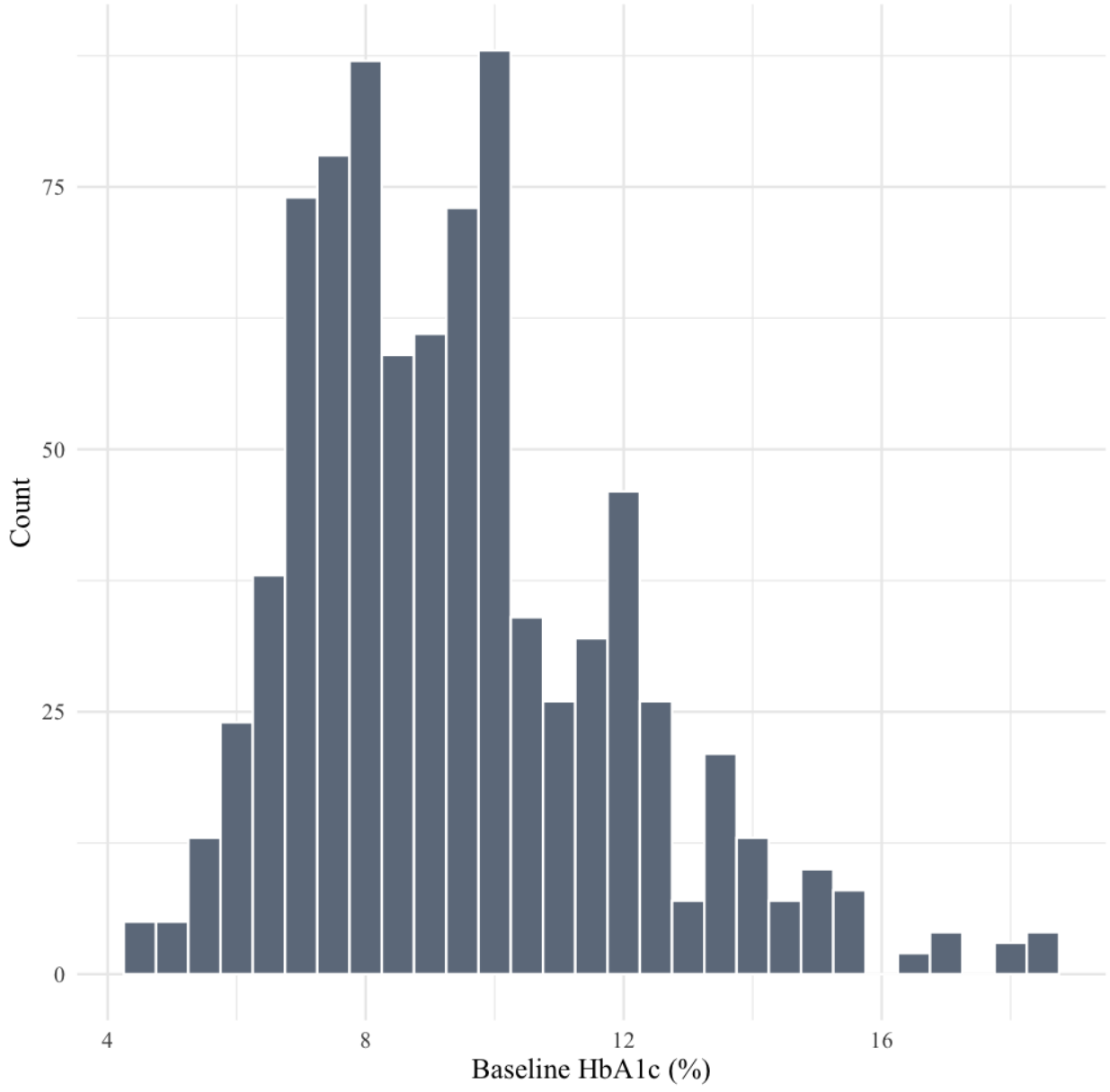


Figure 5

Distribution of psychological encounters

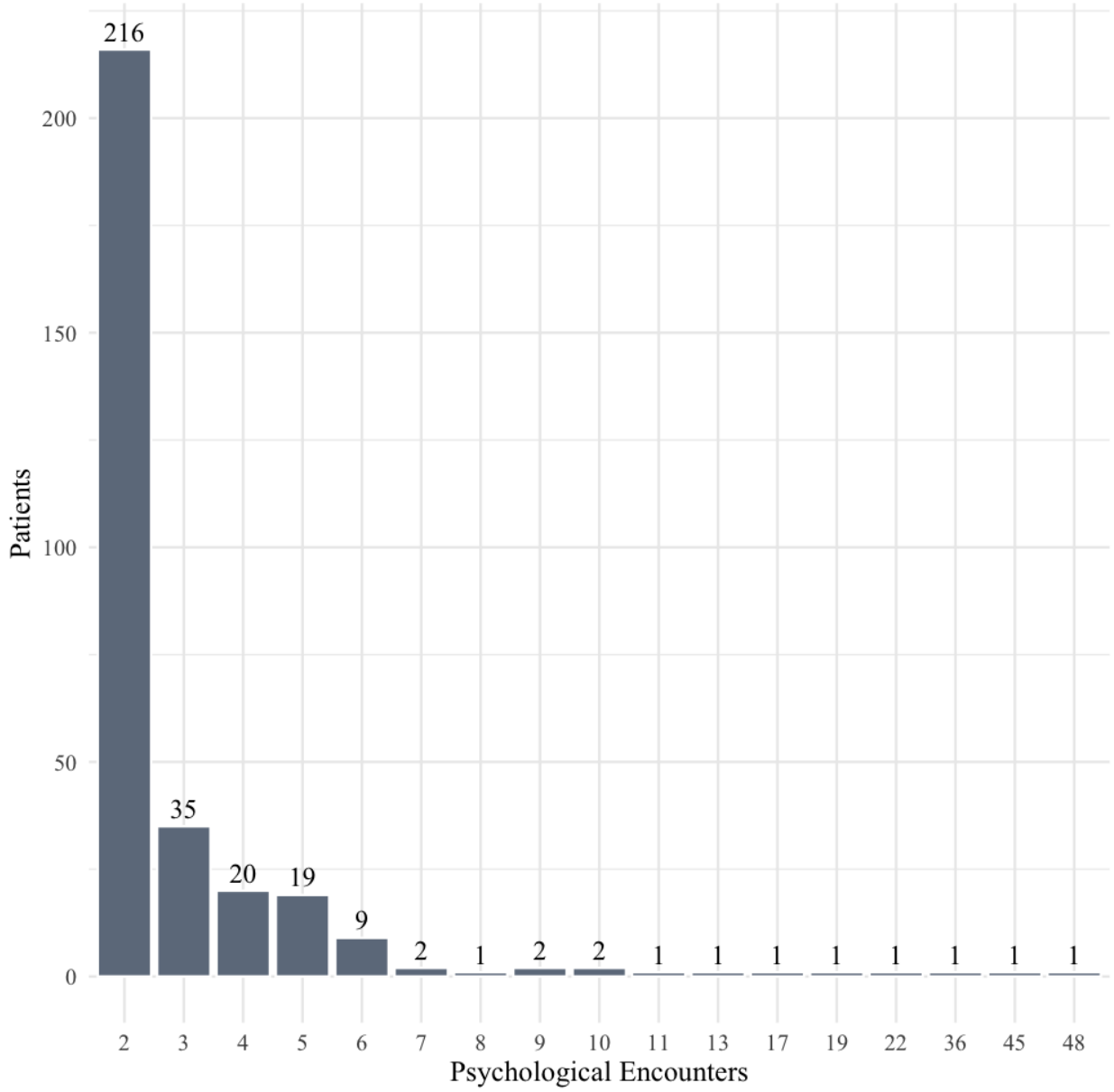


Figure 6

Aim 1: Cubic trend of longitudinal HbA1c

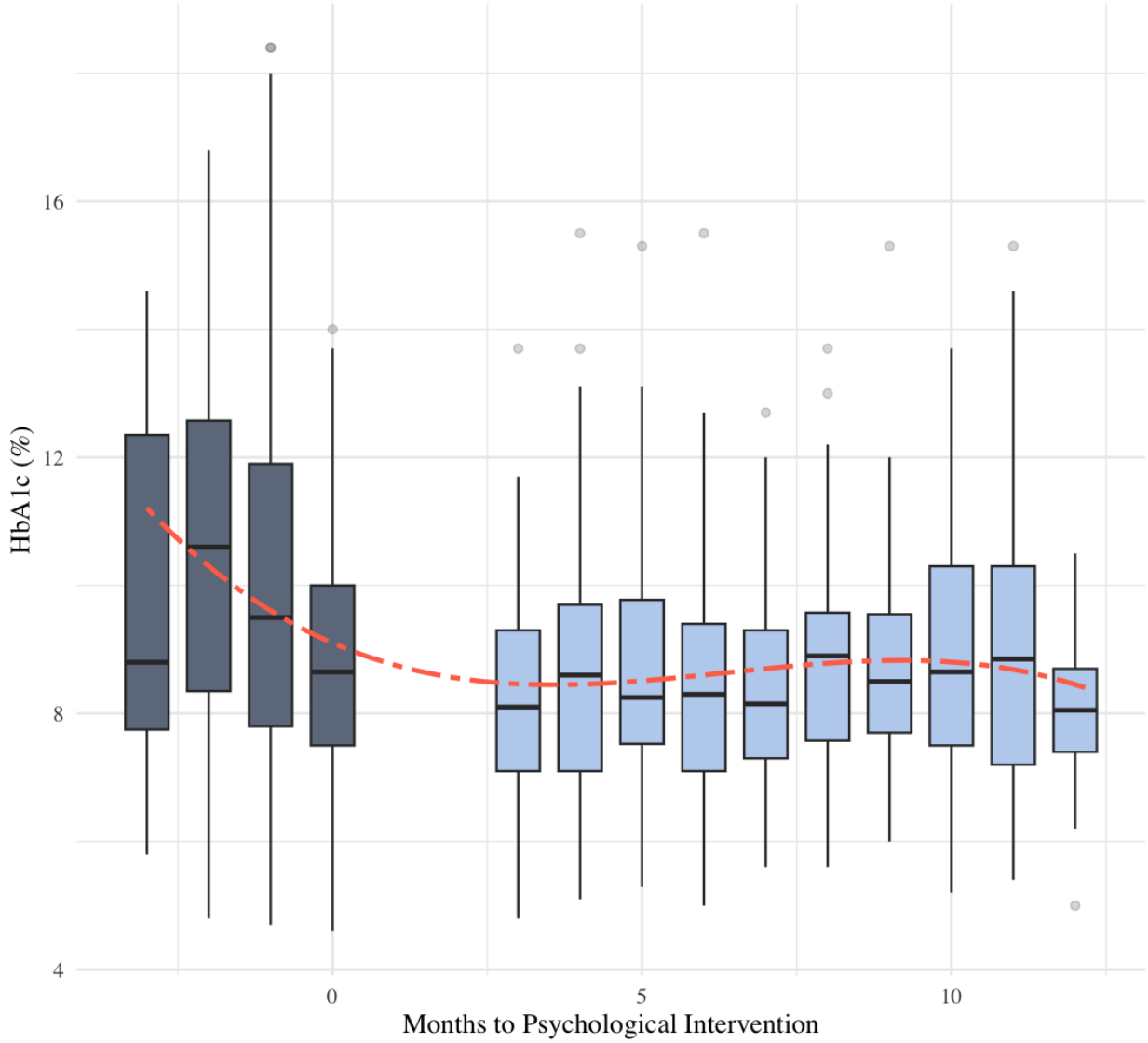


Figure 7

Aim 1 sensitivity analysis: cubic trend of HbA1c among clinically elevated sub-sample

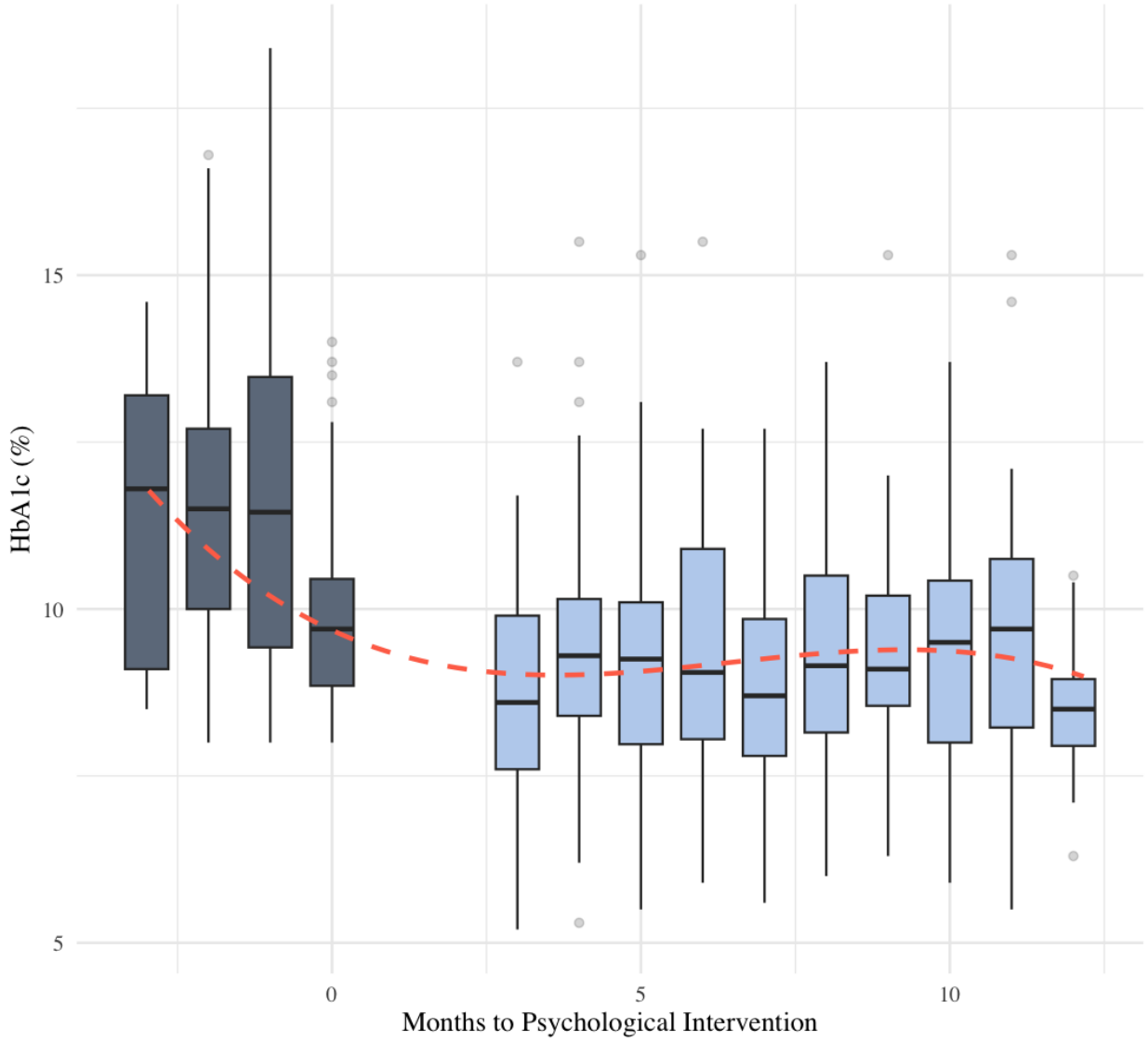


Figure 8

Distribution of psychological encounters (binned)

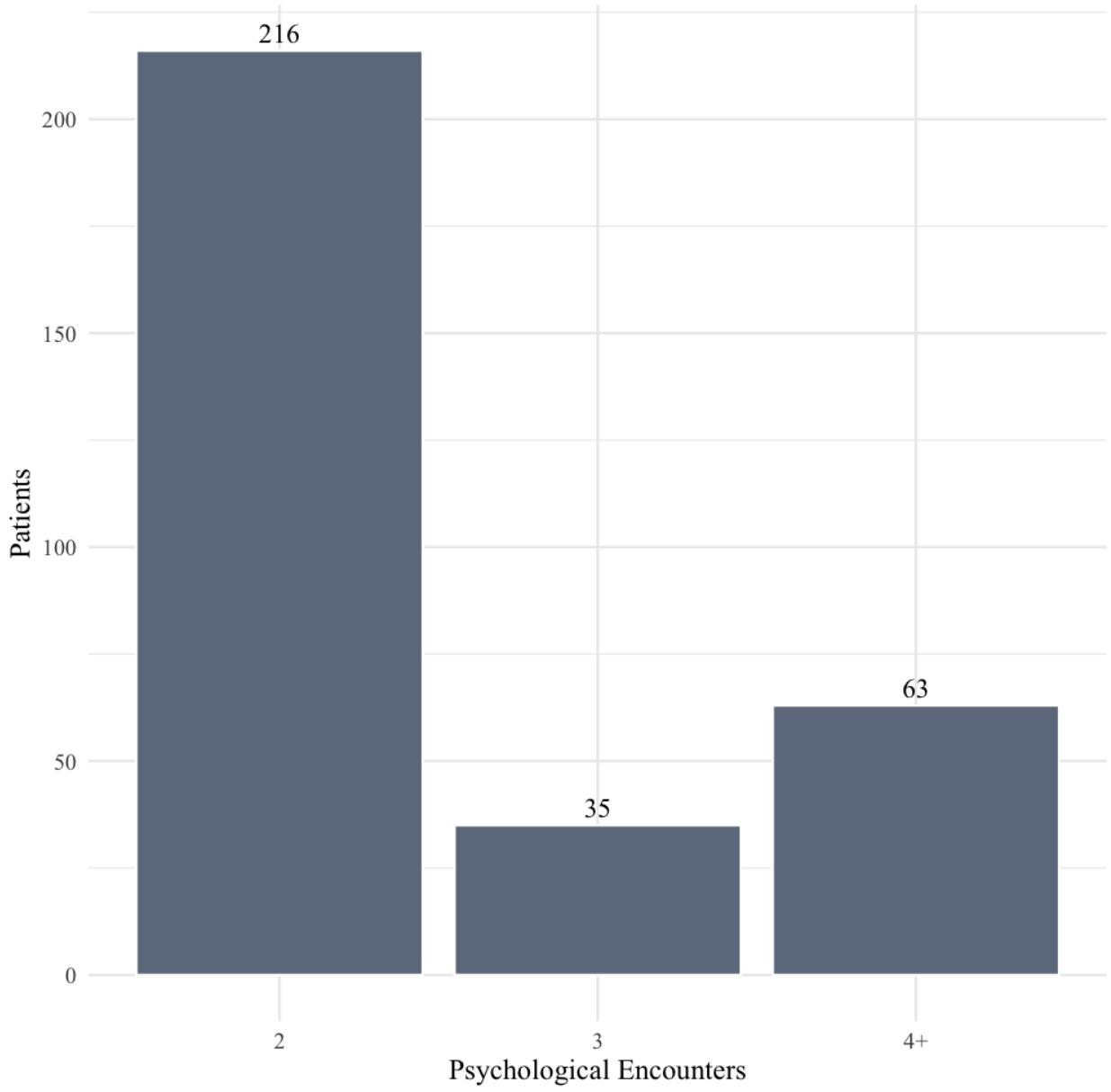
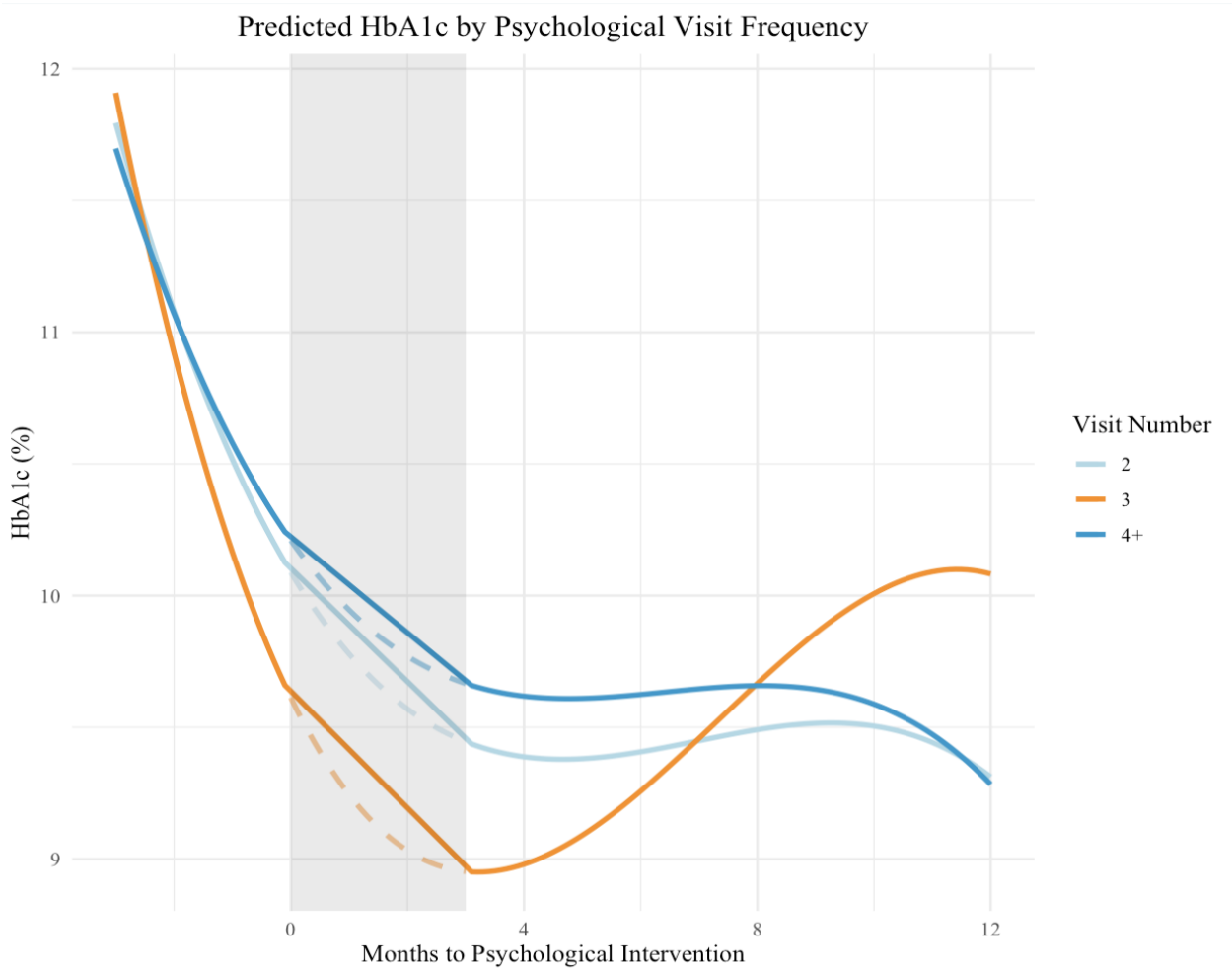


Figure 9

Aim 2: Sensitivity analysis (psychological visits binned)



Note. Dashed line represents predicted trajectories between baseline and first follow-up HbA1c value.

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