Faculty of Medicine and Health Sciences

Effect of an Intensive Outpatient Diabetes Education Programme (IODEP) on Personal, Environmental, and Behavioural Factors, and Glycosylated Haemoglobin Levels in Ghanaians with Type 2 Diabetes

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Effect of an Intensive Outpatient Diabetes Education Programme (IODEP) on Personal, Environmental, and Behavioural Factors, and Glycosylated Haemoglobin Levels in Ghanaians with Type 2 Diabetes

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DECLARATION

I declare that the work in this thesis was carried out in accordance with the regulations of Universiti Malaysia Sarawak. Except where due acknowledgements have been made, the work is that of the author alone. The thesis has not been accepted for any degree and is not concurrently submitted in candidature of any other degree.

……

Signature

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ABSTRACT

Type 2 Diabetes Mellitus (T2DM) prevalence is rapidly increasing in sub-Saharan Africa, with limited evidence for effective diabetes education interventions in low-resource settings. This study evaluated the effectiveness of the Intensive Outpatient Diabetes Education Programme (IODEP), a Social Cognitive Theory-based intervention, on clinical and psychosocial outcomes among individuals with T2DM in Northern Ghana. It also examined the relationships between these factors and their influence on glycemic control. A quasi-experimental design with 245 participants (intervention: n=125; comparison: n=120) was conducted over six months at two hospitals in Ghana: Tamale Teaching Hospital (intervention group) and Tamale Regional Hospital (comparison group). The intervention group received six structured diabetes education modules delivered biweekly/monthly, while the comparison group received standard care. Outcomes included HbA1c levels, diabetes knowledge, self-efficacy, patient involvement, satisfaction with care, social support, provider communication, and self-management behaviors. The intervention achieved significant improvements across multiple domains. HbA1c levels decreased by 1.8% (95% CI: -2.3 to -1.3, $p < 0.001$) in the intervention group compared to the comparison group. Significant improvements were observed in self-efficacy (+15.4 points, $p < 0.001$), social support (+10.2 points, $p < 0.001$), and self-management behaviors (+18.5%, $p < 0.001$). Multiple regression analysis revealed that 71% of HbA1c variance was explained by personal, environmental, and behavioral factors, with self-management behaviors ($\beta = -0.38$) and self-efficacy ($\beta = -0.32$) as the strongest predictors. Mediation analysis confirmed that self-management behaviors mediated the relationships between psychosocial factors and clinical outcomes. The quasi-experimental design limits causal inference capabilities, and the six-month follow-up period may have been insufficient to capture long-term

sustainability of improvements. Self-report measures for behavioral outcomes may have introduced measurement bias, and the disconnect between improved provider communication and glycemic control suggests complex relationships requiring further investigation. The IODEP intervention demonstrated substantial clinical effectiveness in a low-resource setting, with the 1.8% HbA1c reduction representing one of the largest improvements reported for diabetes education interventions in sub-Saharan Africa. The findings validate Social Cognitive Theory's application in this context and identify self-efficacy enhancement and practical skill development as critical intervention components. These results support the integration of structured diabetes education into Ghana's healthcare system and provide a replicable model for other sub-Saharan African countries. This study provides crucial evidence for diabetes care improvement in resource-constrained settings and offers practical guidance for scaling effective diabetes education interventions across sub-Saharan Africa.

Keywords: Type 2 diabetes, diabetes education, Social Cognitive Theory, Ghana, HbA1c, quasi-experimental design, self-efficacy, low-resource settings

Kesan ProgrammePendidikan Diabetes Pesakit Luar Intensif (IODEP) terhadap Faktor Peribadi, Persekitaran, dan Tingkah Laku, serta Tahap Hemoglobin Glikosilat dalam Kalangan Rakyat Ghana dengan Diabetes Jenis 2

ABSTRAK

Prevalens Diabetes Mellitus Jenis 2 (T2DM) meningkat dengan pesat di Afrika sub-Sahara, dengan bukti terhad untuk intervensi pendidikan diabetes yang berkesan dalam persekitaran sumber terhad. Kajian ini menilai keberkesanan ProgrammePendidikan Diabetes Pesakit Luar Intensif (IODEP), sebuah intervensi berasaskan Teori Kognitif Sosial, terhadap hasil klinikal dan psikososial dalam kalangan individu dengan T2DM di Ghana Utara. Ia juga mengkaji hubungan antara faktor-faktor ini dan pengaruhnya terhadap kawalan glisemik. Reka bentuk kuasi-eksperimen dengan 245 peserta (intervensi: n=125; perbandingan: n=120) telah dijalankan selama enam bulan di dua hospital di Ghana: Hospital Pengajaran Tamale (kumpulan intervensi) dan Hospital Wilayah Tamale (kumpulan perbandingan). Kumpulan intervensi menerima enam modul pendidikan diabetes berstruktur yang disampaikan secara dua mingguan/bulanan, manakala kumpulan perbandingan menerima penjagaan standard. Hasil termasuk tahap HbA1c, pengetahuan diabetes, efikasi kendiri, penglibatan pesakit, kepuasan dengan penjagaan, sokongan sosial, komunikasi penyedia perkhidmatan, dan tingkah laku pengurusan kendiri. Intervensi mencapai peningkatan yang signifikan merentasi pelbagai domain. Tahap HbA1c menurun sebanyak 1.8% (95% CI: -2.3 hingga -1.3, $p < 0.001$) dalam kumpulan intervensi berbanding dengan kumpulan perbandingan. Peningkatan yang signifikan diperhatikan dalam efikasi kendiri (+15.4 mata, $p < 0.001$), sokongan sosial (+10.2 mata, $p < 0.001$), dan tingkah laku pengurusan kendiri (+18.5%, $p < 0.001$). Analisis regresi berganda mendedahkan bahawa 71% varians HbA1c dijelaskan oleh faktor peribadi, persekitaran, dan tingkah laku, dengan tingkah laku pengurusan kendiri ($\beta = -0.38$) dan efikasi kendiri ($\beta = -0.32$) sebagai peramal terkuat.

Analisis pengantaraan mengesahkan bahawa tingkah laku pengurusan kendiri mengantarai hubungan antara faktor psikososial dan hasil klinikal. Reka bentuk kuasi-eksperimen mengehadkan keupayaan inferens kausal, dan tempoh susulan enam bulan mungkin tidak mencukupi untuk menangkap kemampanan jangka panjang peningkatan. Ukuran laporan kendiri untuk hasil tingkah laku mungkin telah memperkenalkan bias pengukuran, dan ketidakselarasan antara komunikasi penyedia perkhidmatan yang bertambah baik dan kawalan glisemik mencadangkan hubungan kompleks yang memerlukan penyiasatan lanjut. Intervensi IODEP menunjukkan keberkesanan klinikal yang besar dalam persekitaran sumber terhad, dengan pengurangan HbA1c sebanyak 1.8% mewakili salah satu peningkatan terbesar yang dilaporkan untuk intervensi pendidikan diabetes di Afrika sub-Sahara. Penemuan ini mengesahkan aplikasi Teori Kognitif Sosial dalam konteks ini dan mengenal pasti peningkatan efikasi kendiri dan pembangunan kemahiran praktikal sebagai komponen intervensi kritikal. Hasil ini menyokong integrasi pendidikan diabetes berstruktur ke dalam sistem penjagaan kesihatan Ghana dan menyediakan model yang boleh direplikasi untuk negara-negara Afrika sub-Sahara yang lain. Kajian ini menyediakan bukti penting untuk peningkatan penjagaan diabetes dalam persekitaran terkekang sumber dan menawarkan panduan praktikal untuk meningkatkan skala intervensi pendidikan diabetes yang berkesan merentasi Afrika sub-Sahara.

Kata kunci: *Diabetes jenis 2, pendidikan diabetes, Teori Kognitif Sosial, Ghana, HbA1c, reka bentuk kuasi-eksperimen, efikasi kendiri, persekitaran sumber terhad.*

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
ANOVA	Analysis of Variance
BMI	Body Mass Index
CAT	Communication Assessment Tool
CDIS-P	Clinical Decision-making Involvement and Satisfaction-Patient reported scale
CGM	Continuous Glucose Monitoring
CHWs	Community Health Workers
CI	Confidence Interval
COVID	Coronavirus Disease
CVDs	Cardiovascular Diseases
DAWN	Diabetes Attitudes, Wishes and Needs
DCCT	Diabetes Control and Complications Study
DCF	Diabetes Care Profile
DE	Design Effect
DESMOND	Delivering the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DKA	Diabetes Kato-Acidosis
DPP	Diabetes Prevention Programme
DSME	Diabetes Self-Management Education
DSMES	Diabetes Self-Management Education and Support
DSMQ	Diabetes Self-Management Questionnaire
EASD	European Association for the Study of Diabetes
GHS-ERC	Ghana Health Service-Ethics Review Committee

EKF	Entwicklung, Konstruktion und Fertigung
FINDRISC	Finnish Diabetes Risk Score
FPG	Fasting Plasma Glucose
GBD	Global Burden of Disease
GNI	Gross National Income
GSE	General Self-Efficacy Scale
HRQOL	Health-Related Quality of Life
HbA1c	Glycosylated Haemoglobin
IDF	International Diabetes Federation
IFCC	International Federation of Clinical Chemistry
IHME	Institute for Health Metrics and Evaluation
IODEP	Intensive Outpatient Diabetes Education Programme
IRB	Institutional Review Board
LMICs	Low- and Middle-Income Countries
NCDs	Non-Communicable Diseases
NEGD	Non-Equivalent Groups Designs
NHIS	National Health Insurance Scheme
OGTT	Oral Glucose Tolerance Test
PA	Physical Activity
PI	Principal Investigator
PDSME	Persian Diabetes Self-Management Education
SCT	Social Cognitive Theory
SDM	Shared Decision Making
SKILLD	Spoken Knowledge in Low Literacy in Diabetes

SMS	Short Messaging Service
SSA	Sub-Saharan Africa
TAMA	Tamale Metropolitan Area
T2DM	Type-2 Diabetes Mellitus
TREND	Transparent Reporting of Evaluations with Non-Randomized Designs
TRH	Tamale Regional Hospital
TTH	Tamale Teaching Hospital
UDS	University for Development Studies
UK	United Kingdom
UKPDS	United Kingdom Prospective Diabetes Study
VU	Vrije Universiteit Amsterdam
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Study Background

Type-2 Diabetes Mellitus (T2DM) affects over 90% of the global diabetic population, which exceeds 451 million individuals. Globally, diabetes is a significant contributor to morbidity and mortality (Cho et al., 2018; International Diabetes Federation [IDF] (2021). According to the IDF (2021), over five million individuals between the ages of 20 and 79 succumb to the disease or its associated complications annually. The prevalence of diabetes is expected to increase in the future, with estimates putting it at 693 million by 2045 (IDF, 2021). Ghana is one of the 48 countries of the IDF African region where in 2024, 25 million of people were said to be living with diabetes in the African Region and this is estimated to be around 60 million by 2050. In Ghana, prevalence of diabetes among adults is about 2.7% (IDF African Region, 2024).

A comprehensive review of research by Kazibwe et al. (2024) found that the prevalence of diabetes at the national level in Ghana ranged from 2.80% to 3.95%. At the regional level, the Western region had the largest prevalence (39.80%), followed by the Ashanti region (25.20%), the Central region (24.60%), and Northern region (24%) (Kazibwe et al., 2024; Mogre et al., 2014). Women were more likely to get diabetes than males. Diabetes was shown to be more prevalent in urban areas than in rural areas (Kazibwe et al., 2024). Also, diabetes admission rates rose from 2.36 per 1000 in 1983 to 14.94 per 1000 in 2014 ($p<0.0001$ for linear trend), a 633% increase over the 31-year period. Inpatient diabetes mortality rates rose from 7.6 per 1000 deaths in 1983 to 30 per 1000 deaths in 2012 (Sarfo-Kantanka et al., 2016). Thus, diabetes admission and death rates in Ghana have gone up

significantly during the last four decades. Despite this, diabetes self-management education implemented are found to be under-resourced and haphazard. Diabetes self-management knowledge, albeit limited, are linked to self-management actions. To reduce the poor case fatality associated with diabetes in resource-limited settings, Sarfo-Kantanka et al. (2016) recommended diabetes self-management education (DSME) interventions in low-resource settings should be culturally tailored and include more intensive structured education on the risk factors for diabetes, acute diabetes care, and the implementation of hospital guidelines for the disease control and the reduction of modifiable risk factors.

Several studies (UK Prospective Diabetes Study [UKPDS] Group, 1998; Selvin et al., 2004; Almutairi et al., 2019; American Diabetes Association [ADA], 2021; IDF, 2021) have demonstrated that insufficient disease control, as indicated by elevated glycosylated hemoglobin (HbA1c) levels, is associated with an elevated risk of costly metabolic disorders, including microvascular and macrovascular diabetic complications. Limited access to early diabetes diagnosis and treatment can exert significant consequences across varied aspects of healthcare and patient outcomes, including clinical inertia (defined as the failure of a health-care provider to start or intensify therapy when therapeutic goals are not met, and it is thought to be one of the significant causes of uncontrolled diabetes (Almigbal et al., 2023; Ziemer et al., 2005), inadequate patient education and support upon diagnosis, poor disease-specific knowledge and understanding, suboptimal self-management behaviours, nonadherence to treatment recommendations, limited patient engagement in their care process, increase risk of complications, among others (Phillips et al., 2001; Ziemer et al., 2005; Chrvala et al., 2016; Powers et al., 2015; Rashed et al., 2016; Afaya et al., 2020). As a concept, patient engagement focuses on an interdependent partnership between patients and healthcare professionals, in which patients are empowered with information, tools, and encouragement

to be engaged partners in decision-making relative to their care and management processes (ADA, 2021; Clavel et al., 2021).

The ADA's latest treatment recommendations prioritize a personalized and patient-centered approach to optimize diabetes management (ADA, 2021; 2022; 2023). This approach involves patient participation in treatment decision-making that aligns with their preferences and values. Individuals with T2DM possess unique perspectives derived from their personal experiences in managing the disease, which can provide invaluable insights. Patients' individual experiences, and cognitive traits (including beliefs, values, knowledge, awareness of their disease, and self-efficacy), can impact their willingness and readiness to engage in their care (Chrvala et al., 2016; Powers et al., 2015; Rashed et al., 2016).

Patients who are well-informed or empowered are more inclined to openly communicate positive and negative experiences with their clinicians and are also more likely to adhere to the prescribed treatment plan (Powers et al., 2015). Patient outcomes are influenced by both adherences to recommended criteria and patient involvement in developing these recommendations (Entwistle et al., 2008; Department of Health, 2012; Good Medical Practice, 2013). Patient participation is a collaborative process where individuals with T2DM and their healthcare providers make medical decisions together. This process considers the values, interests, and personal circumstances of the patients (Entwistle et al., 2008; Vahdat et al., 2014). Effective patient involvement has been consistently associated with several benefits, including increased patient empowerment, reduced risk of diabetes complications, improved well-being, and good health (Institute of Medicine, 2011; Lee et al., 2016; Powers et al., 2015).

Patient engagement in disease management is a process aimed at empowering patients to actively participate in their healthcare by sharing information, emotions, and symptoms, adhering to medical advice, and expressing their perspectives on treatment options. This phenomenon is based on the significance of offering patients support and education as an initial step towards empowering them to take control of their treatment (Entwistle et al., 2008; Vahdat et al., 2014; Powers et al., 2015). Rather than adopting a paternalistic stance towards healthcare, promoting sufficient education and support enables patients to actively participate in the management of their healthcare in partnership with healthcare professionals. Education and support interventions should encompass the stages of interpersonal interactions, knowledge acquisition, and decision-making.

Providing patients with necessary information and support to make informed treatment decisions is essential for various reasons. Patients and healthcare professionals often have different interpretations of illness processes, resulting in divergent treatment expectations and outcomes. Furthermore, it is imperative to tailor treatment options to individuals with diverse educational levels, literacy levels, cultural backgrounds, ages, genders, and other individual characteristics. There is global concern regarding inadequate care and the resulting diabetic complications (Digssie et al., 2020; Kumah et al., 2021). Proper education and support are essential to ensure that the patient's care plan aligns with their priorities. Furthermore, considering the limited duration of patient visits to medical facilities, it is crucial to offer patients the necessary education and support to effectively self-manage their health outside of the clinical setting (ADA, 2018; Powers et al., 2015). When multiple feasible alternatives exist or when a clear-cut course of action is elusive, education and support are appropriate interventions.

Historically, studies among healthcare professionals in the United States reported healthcare professionals' unwillingness to provide patients with detailed information regarding their diagnosis, prognosis, and available treatments due to concerns that such disclosures were going to induce fear, anxiety, and depression, potentially compromising patient outcomes (Girgis & Sanson-Fisher, 1995; Oken, 1961). Over time, evidence-based practice has shown that an informed and collaborative decision-making approach is more effective and promotes patient-centered care (Powers et al., 2015). Various research has shown that patients who receive adequate education and support during clinical visits are more likely to actively manage their health and experience better health outcomes (Greenfield et al., 1985; 1988; Kaplan et al., 1989; Powers et al., 2015; Chrvala et al., 2016).

The primary goal of treating patients with T2DM is to enhance their overall health and well-being, while also minimizing symptoms and preventing associated complications (ADA, 2022). Patient education and support are essential for enhancing patient understanding of the aetiology, current status, and prognosis of their disease, as well as providing guidance on managing these challenges (Powers et al., 2015; Chrvala et al., 2016; ADA, 2022). The recommended approach for managing patients with T2DM prioritizes holistic patient care rather than solely focusing on the disease itself (Ofori & Unachukwu, 2014). Diabetes self-management education and support interventions are recommended for addressing the educational and support needs in low-income economies (Powers et al., 2015). These programmes aim to assist, motivate, and provide support to patients in identifying their healthcare needs and promptly seeking medical care.

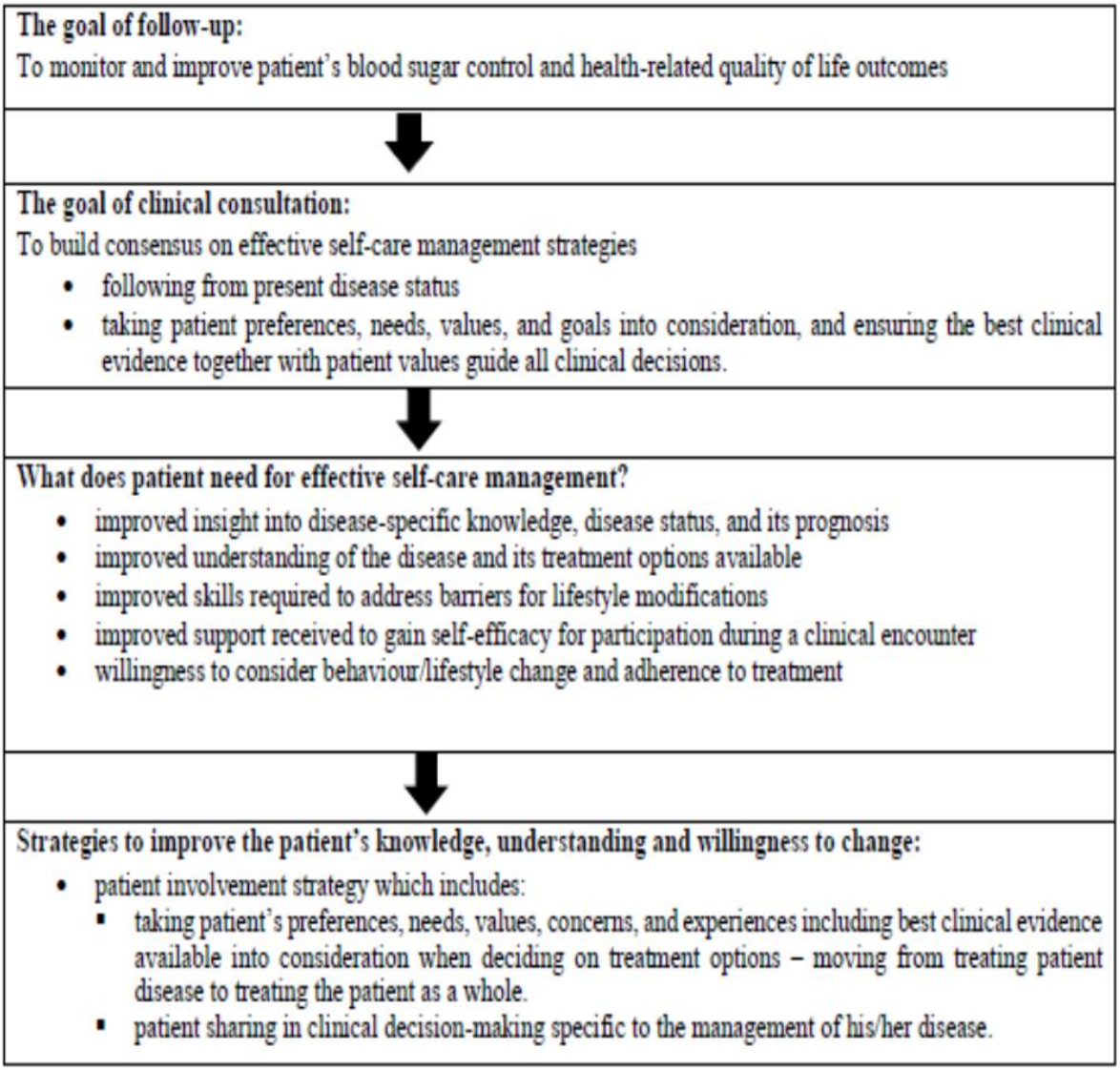

Figure 1.1: A framework of the Clinician Office Visit

1.2 Problem Statement

Type 2 diabetes mellitus (T2DM) has emerged as a critical public health challenge in Ghana, with current prevalence estimates of 6.5% affecting approximately 2.4 million adults—representing one in every 15 Ghanaians (Kazibwe et al., 2024; WHO Regional Office for Africa, 2024). This prevalence substantially exceeds the African average and is projected to increase by 129% by 2045, positioning Ghana among the countries with the highest diabetes burden in sub-Saharan Africa (Obirikorang et al., 2025; Adjei et al., 2024). The

epidemiological transition is characterized by significant regional disparities, with urban areas experiencing disproportionately higher prevalence rates and the Western Region recording alarming rates of 39.8% (Swaray et al., 2025).

The management of T2DM in Ghana is severely compromised by a constellation of interconnected systemic barriers that perpetuate suboptimal glycemic control. Over 60% of patients exhibit HbA1c levels above recommended thresholds, significantly exceeding global averages (Adjei et al., 2024; Swaray et al., 2025). Critical management challenges include: (i) limited health literacy and numeracy skills that impede effective self-management behaviors (Akubire et al., 2025); (ii) pervasive cultural beliefs attributing diabetes to spiritual causation, which delays biomedical treatment seeking and promotes reliance on traditional remedies (Boamah et al., 2024; Asante et al., 2025); (iii) economic constraints limiting access to medications, glucose monitoring supplies, and specialized care (Greenfield et al., 2024); and (iv) healthcare system inadequacies characterized by insufficient trained practitioners, poor consultation infrastructure, and absence of structured diabetes education programmes (Lamptey et al., 2022; Kumah et al., 2021).

Structured diabetes self-management education and support (DSMES) interventions have demonstrated robust efficacy in developed countries, with meta-analyses showing mean HbA1c reductions of 0.83% and significant improvements in self-care behaviors (Osei et al., 2025; Smith et al., 2025). However, the effectiveness of these evidence-based interventions remains largely unestablished in low-resource settings characterized by limited health literacy, diverse cultural contexts, and resource constraints (Asante et al., 2024). The existing literature reveals a critical knowledge gap regarding the adaptation, implementation, and effectiveness of culturally tailored DSMES interventions specifically designed for the

Ghanaian healthcare context and patient population (Sarkodie, 2019; Lamptey et al., 2022), especially vulnerable diabetic population.

The Intensive Outpatient Diabetes Education Programme (IODEP) represents an innovative, theoretically grounded intervention specifically designed to address the multidimensional challenges of T2DM management in Ghana. IODEP is conceptually anchored in Bandura's Social Cognitive Theory (SCT), which posits that behavior change occurs through the dynamic interaction of personal, environmental, and behavioral factors (Bandura, 2004; Ghoreishi et al., 2019). The intervention systematically targets the three core SCT constructs: (i) personal factors including patient involvement in treatment decision-making, comprehensive diabetes knowledge acquisition, decision-making self-efficacy enhancement, and satisfaction with care delivery; (ii) environmental factors encompassing structured social support from healthcare providers and optimization of provider communication styles to facilitate effective patient-provider interactions; and (iii) behavioral factors focusing on practical diabetes self-management skills including glucose monitoring, dietary adherence, physical activity engagement, medication compliance, and foot care practices (Chen et al., 2015; Yari et al., 2023). This theoretical framework provides a robust foundation for addressing the complex interplay of cognitive, social, and behavioral determinants that influence diabetes self-management in the Ghanaian context (Thojampa et al., 2019).

1.3 Conceptual Framework of the Study

The Social Cognitive Theory (SCT), developed by Albert Bandura in 1986, provides an in-depth structure and a robust conceptual framework for understanding how people acquire, process, and apply information within the social context (Bandura, 1986; Bandura, 1998;

Govindaraju, 2021). The theory emphasizes the interaction between personal factors, environmental influences, and behaviour (see Figure 1.2). SCT asserts that effective learning has to take place within a social context which is characterized by reciprocal and dynamic interaction of the individual, their environment, and behaviour (Bandura, 1986; Bandura, 1998; Luszczynska & Schwarzer, 2005). Hence, SCT is unique due to its focus on social influence, including both internal and external social reinforcement.

The key philosophical concepts undergirding SCT are a) Observational learning - which refers to individuals acquiring new behaviours or skills by closely watching and imitating the actions of others (role models) in a social context; b) Reciprocal determinism - a central concept of SCT with its emphasis on the dynamic interplay between personal factors, behaviour, and the environment; and c) Self-efficacy, which is a distinguishing factor in SCT, shaped by an individual's unique abilities and personal circumstances, as well as external factors that can either hinder or support their progress (Bandura, 1986; Bandura, 1998; Luszczynska & Schwarzer, 2005). In this regard, SCT can offer a robust framework for understanding how people learn and manage chronic diseases like diabetes. First, individuals learn effective diabetes management through observational learning, i.e., newly diagnosed patients can benefit from peer-led educational interventions, by observing and gaining insights into dietary adjustments, physical activity, and medication adherence. Second, effective diabetes management also relies heavily on self-efficacy, which is the confidence in one’s ability to perform specific tasks. Higher self-efficacy leads to better adoption of positive health behaviours. Third, self-regulation is also an important concept, and it relates to setting realistic goals, creating action plans, and monitoring progress (e.g. a patient might set a goal to walk for 15 minutes after each meal). Clear, actionable plans help achieve these goals, such as scheduling walks, ensuring proper footwear, and choosing a

nearby park. Monitoring health parameters, like blood glucose levels, is also crucial. Additionally, patients can use tools like glucose meters, apps, or diaries to track their progress.

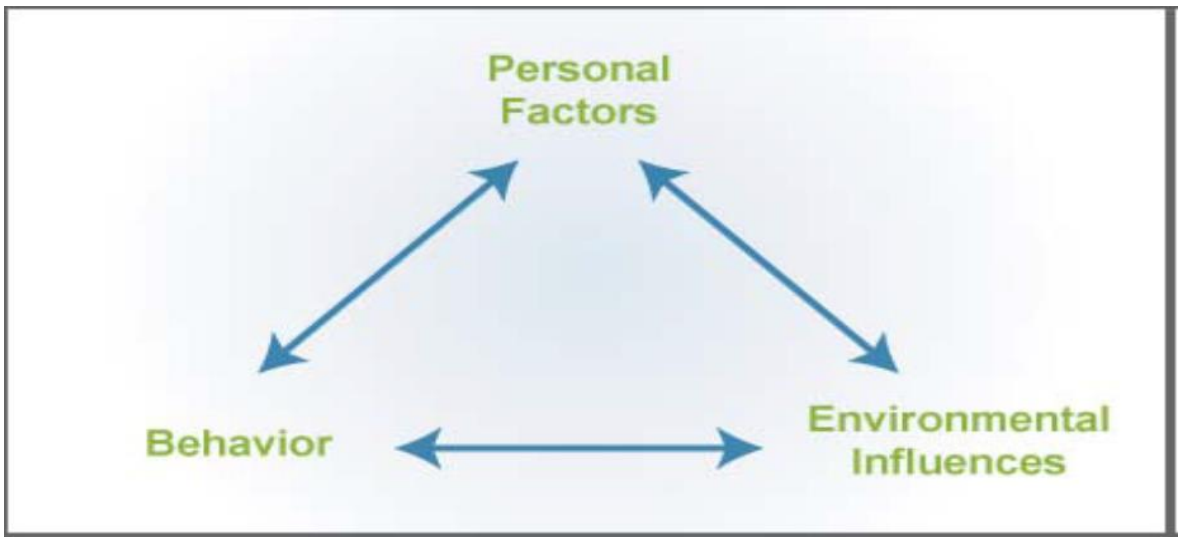

Figure 1.2: The Social Cognitive Theory Model

Putting all these concepts undergirding SCT together, there are three interacting influences which can have a significant impact on individuals' experiences and outcomes in diabetes care, i.e., personal, environmental, and behavioural influences (Luszczynska & Schwarzer, 2005). As depicted in the conceptual framework (Figure 1.3), briefly, the variables under each of these 3 domains or influences examined are described in the following paragraph.

Personal factors capture the patient's internal resources and psychological state. These include involvement in decision-making, which reflects autonomy and empowerment; disease-specific knowledge, which provides the foundation for informed self-care; decision-making self-efficacy, or confidence in making appropriate choices; and satisfaction with decisions, which reinforces ongoing engagement and adherence. Environmental factors emphasize the role of external support systems and healthcare interactions. Social support

encompasses emotional, affirmative, instrumental, and informational dimensions, while provider communication style—welcoming, facilitative, educative, and non-judgmental—fosters trust, collaboration, and effective information exchange. At the core are self-management behaviors, which mediate the effects of personal and environmental influences. These include self-monitoring of blood sugar, healthy eating, regular physical activity, appropriate healthcare use, and medication adherence. Each behavior reflects the patient's ability to integrate knowledge, confidence, and support into daily practice.

In summary, the conceptual framework for this study, informed by SCT, considers personal factors, environmental influences, and behaviour. These factors are crucial for empowering individuals with T2DM to actively participate in their diabetic care. Given the complexities of these factors, there is a clear need for a comprehensive educational interventional programme to address these factors holistically. The intensive outpatient diabetes education programme (IODEP) was designed to address each of these factors (personal, behavioural, and environmental factors) in the SCT framework, which are critical to managing T2DM. By improving glycaemic control, the IODEP aims to enhance patients' well-being and reduce treatment costs by minimizing risks of complications. Therefore, understanding the reciprocal association between behavioural, environmental, and personal factors and HbA1c is crucial for the success of these educational interventions (Bandura, 1997; Smith, 2021).

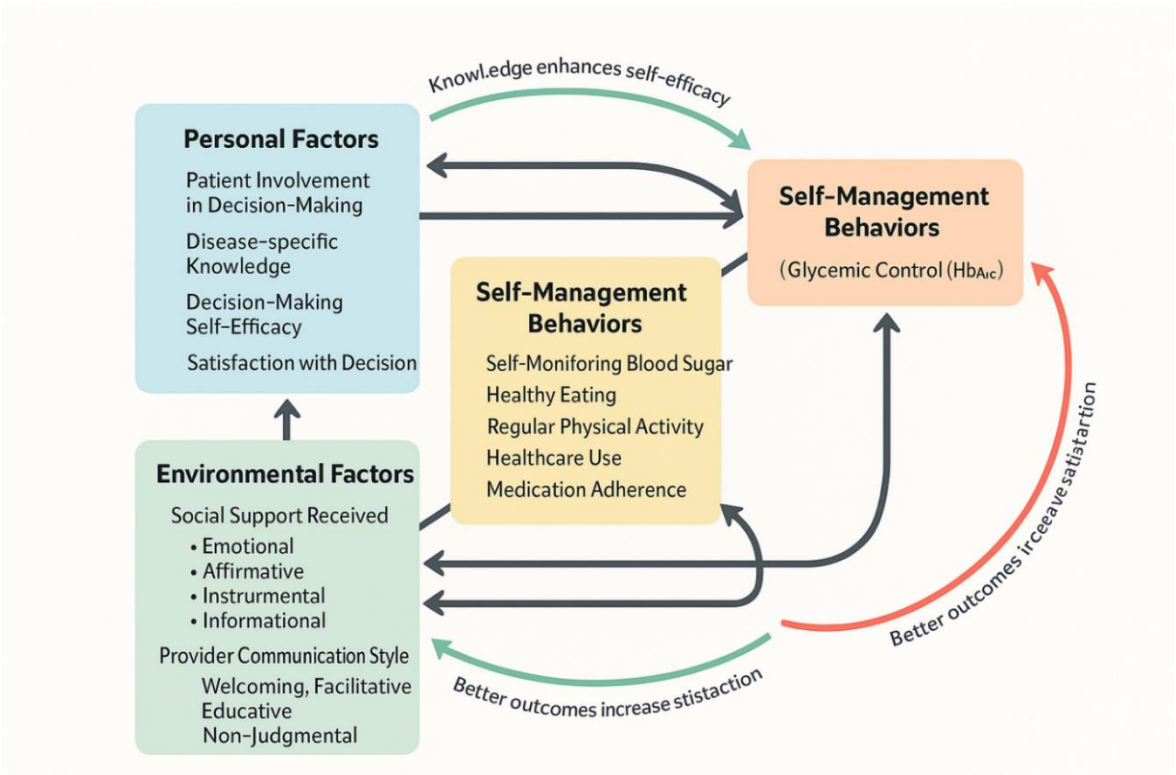

Figure 1.3: Conceptual Framework for the Study

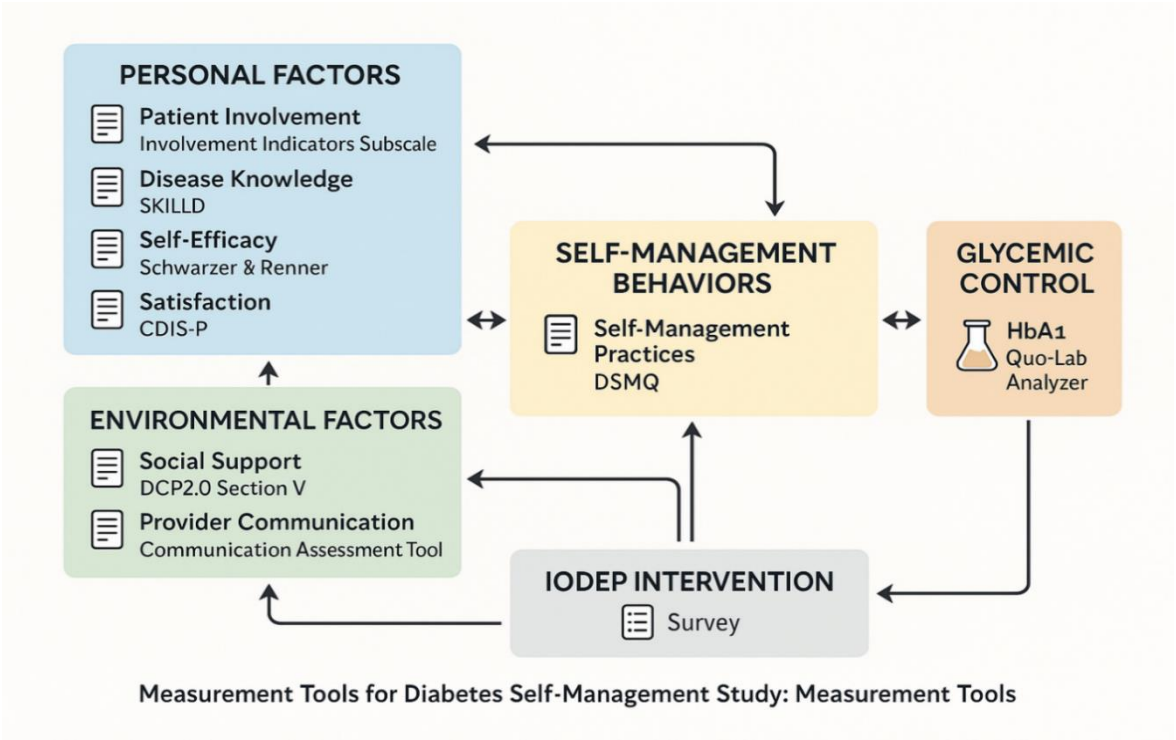

Figure 1.4: Tools for Measuring Study Variables

The framework highlights the bidirectional relationships between personal, environmental, and behavioral components of diabetes care. Personal factors such as knowledge and self-efficacy support better self-management, while successful self-management in turn builds confidence and satisfaction. Similarly, strong social support and effective provider communication promote healthier behaviors, while patients who demonstrate good self-management often receive more support and positive interactions. Self-management behaviors also influence glycemic control, with improved HbA1c reinforcing the value of continued effort. These dynamics are sustained through feedback loops. Knowledge enhances self-efficacy and stimulates further learning, while better outcomes increase satisfaction and strengthen engagement. Improved outcomes also encourage greater involvement from family and providers, reinforcing environmental support. Together, these loops can create positive cycles of improvement or, conversely, negative spirals when poor outcomes reduce satisfaction and engagement. Importantly, social support, effective communication, and environmental adjustments can act as balancing mechanisms to interrupt downward trends. The framework also incorporates a temporal dimension, capturing how psychosocial factors and glycemic outcomes evolve over time. Within the six-month IODEP intervention, assessments at baseline, three months, and six months provide insights into both intermediate progress and sustained behavior change.

1.4 Significance of the Study

Type 2 Diabetes Mellitus (T2DM) represents a rapidly escalating health crisis in sub-Saharan Africa, with the region experiencing the world's fastest growth in diabetes prevalence—projected to increase by 129% by 2045 (International Diabetes Federation, 2021). Ghana exemplifies this challenge, with diabetes prevalence rising from 2.0% to 3.9% between 2000-2019 and (Asamoah-Boaheng et al., 2019), yet fewer than 30% of adults with diabetes

achieve adequate glycemic control compared to 50-60% in high-income countries (Atun et al., 2017; de-Graft Aikins et al., 2010). This poor control contributes to diabetes being the second leading cause of death in Ghana, claiming approximately 9,000 lives annually (Institute for Health Metrics and Evaluation, 2019).

The disparity in diabetes outcomes reflects fundamental differences in care delivery models. While high-income countries have integrated structured diabetes education into routine care—achieving 0.5-1.5% HbA1c reductions and 20-40% complication reductions (Norris et al., 2002; Steinsbekk et al., 2012)—such evidence-based interventions remain virtually absent from sub-Saharan African healthcare systems (Atun et al., 2017). Ghana's diabetes care follows a traditional biomedical model focused on clinical monitoring and medication adjustment, with minimal attention to patient education or self-management support (Beran et al., 2005; Kengne & Mayosi, 2014).

This education gap is particularly problematic given that effective diabetes management requires patients to make complex daily decisions about diet, physical activity, and medication—decisions requiring knowledge, skills, and confidence are rarely addressed in routine clinical encounters (Funnell & Anderson, 2004; Powers et al., 2015). The challenge extends beyond simply translating existing programmes, as cultural, social, and economic contexts profoundly influence health behaviors, necessitating interventions grounded in robust behavioral theory and adapted to local realities (Glasgow et al., 2003; Whittemore, 2007).

Social Cognitive Theory provides a particularly relevant framework for understanding diabetes self-management in sub-Saharan Africa, as it recognizes the reciprocal interactions between personal factors (knowledge, self-efficacy), environmental factors (social support,

healthcare systems), and behavioral factors (self-management practices) (Bandura, 2004). This framework is especially pertinent in Ghana's collectivist culture, where family relationships significantly influence health decisions and hierarchical provider-patient relationships may inhibit patient engagement (Aikins, 2005; Beach et al., 2006).

Despite urgent need, the evidence base for diabetes education in sub-Saharan Africa remains remarkably thin, with fewer than 15 rigorous studies identified across the entire region (Mwangi et al., 2020). This evidence gap has profound implications for policy and practice, as healthcare systems lack guidance for implementing effective programmes, and the absence of locally validated interventions perpetuates problematic practices of importing programmes without adequate cultural adaptation (Beran et al., 2005; Motala et al., 2022).

The Intensive Outpatient Diabetes Education Programme (IODEP) study addresses these critical gaps by developing and rigorously evaluating a Social Cognitive Theory-based diabetes education intervention specifically designed for the Ghanaian context. The study's significance extends beyond immediate clinical outcomes to provide theoretical validation, implementation science insights, policy evidence, capacity building for sustainable diabetes care improvement (Glasgow et al., 2003; Wagner et al., 2001), to its alignment with Ghana's commitment to the Sustainable Development Goals (SDGs), primarily SDG 3.4, reducing early deaths from non-communicable diseases through better prevention and treatment (United Nations, 2015).

By demonstrating that rigorous, theory-based diabetes education interventions can achieve meaningful clinical improvements in low-resource settings, the IODEP study challenges assumptions about comprehensive diabetes care feasibility in sub-Saharan Africa and provides a foundation for scaling effective interventions across the region (Atun et al., 2017;

Kengne & Mayosi, 2014). This research represents a significant contribution to addressing one of the most pressing health challenges facing sub-Saharan Africa in the 21st century.

1.5 Hypotheses

The following research hypotheses were proposed to evaluate the impact of the Intensive Outpatient Diabetes Education Programme (IODEP) on HbA1c levels and key constructs of the Social Cognitive Theory (SCT):

i. Glycemic Control (HbA1c Levels)

   a. H1: Participants who undergo the IODEP intervention will demonstrate a significant decline in HbA1c levels compared to comparison/standard care group.

ii. Personal Factors

   a. H2: Participants in the IODEP intervention group will show a significant improvement in patient involvement in treatment decision-making, diabetes knowledge, decision-making self-efficacy, and satisfaction with care compared to the comparison group.

iii. Environmental Factors

   a. H3: Participants in the IODEP group will report greater perceived social support from healthcare providers for diabetes self-management and perceive better provider-patient communication than those in the comparison group.

iv. Behaviour Factors

a. H4: Participants exposed to the IODEP intervention will show significant improvements in self-management behaviours, including dietary adherence, physical activity, medication adherence, and regular blood glucose monitoring, compared to the comparison group.

b. H5: Improvements in personal, environmental, and behaviour factors will be significantly associated with reductions in HbA1c levels among participants in the IODEP intervention group.

The Research Questions:

i. What are the differences in HbA1c levels between T2DM patients receiving IODEP intervention group compared to those in the standard care group?

ii. What effect does the IODEP has on the personal factors within the SCT framework for T2DM management?

iii. What effect does the IODEP has on environmental factors within the SCT framework for T2DM management?

iv. What effect does the IODEP has on behaviour factors within the SCT framework for T2DM management?

v. What effects does personal, environmental, and behavioural factors within the SCT framework have on the HbA1c levels in patients with T2DM?

1.6 Objectives

1.6.1 General Objectives

The overarching objective of this study was to assess the effect of an Intensive Outpatient Diabetes Education Programme (IODEP) on personal, environmental, and behaviour factors, as well as HbA1c levels, in individuals Ghanaians diagnosed with type 2 diabetes mellitus (T2DM) in Ghana.

1.6.2 Specific Objectives

i. To determine the effect of IODEP on HbA1c levels of T2DM patients in the intervention group as compared to the standard care group at baseline and six months post intervention.

ii. To determine the effect of IODEP on personal factors within the SCT framework in the intervention group as compared to the standard care group at baseline and six months post intervention

iii. To determine the effect of IODEP on environmental factors within the SCT framework in the intervention group as compared to the standard care group at baseline and six months post intervention

iv. To determine the effect of IODEP on behavioural factors within the SCT framework in the intervention group as compared to the standard care group at baseline and six months post intervention

v. To determine the effect of personal, environmental, and behavioural factors within the SCT framework on HbA1c levels in the intervention group as

compared to the standard care group at baseline and six months post intervention.

1.7 Organization of Thesis

The thesis comprises of five (5) chapters. Chapter one starts with introduction, followed by background and context of the study, statement problem, research questions, research objectives, the purpose of the study, significance of the study, limitations of the study as well as the organization of the study.

Chapter two provides the literature review for the study. Among others, the review examines the determinants of glycemic control among T2DM patients. Significantly, it looked at the constructs of social cognitive theory (defined to include, personal factors—i.e., knowledge, self-efficacy, satisfaction, and patient involvement treatment decisions; environmental factors—i.e., provider's communication style, provider's support; and behaviour—i.e., self-management behaviours) and diabetes control. Again, literature on intervention effect on personal factors, on environmental influences, on behaviour, and on glycosylated hemoglobin level were also reviewed.

Chapter three also provides the methodology including the study design and setting, study variables and the tools used in measuring them, study population, the sample size, the intervention (Intensive Outpatient Diabetes Education Programme (IODEP)), and the data analysis procedures adopted for the study. Chapter four presents study results systematically and in line with the study objectives—that is, to answer the research objectives determined at the outset.

Chapter five gave a detailed discussion of the research findings and situating it within the context of existing literature and aligning with the conceptual framework of the research. Among other things discussed include the practical and theoretical implications of the study finding, the study limitations, and future directions. Recommendations on the research findings and conclusions are offered as well as suggestions for further research.

1.8 Chapter Summary

This chapter introduces the study by presenting the background of the study and the problem statement, including the conceptual framework of the study. Further, the chapter provides the significance of the study, the study hypothesis, research questions, aim and objectives of the study and the organization of the study specifying the contents of each of the five chapters of the research.

CHAPTER 2

LITERATURE REVIEW

2.1 T2DM Epidemiology

Chronic non-communicable diseases, such as diabetes, and hypertension, among others, are significant public health concerns, especially in low- and middle-income countries (LMICs) (Zheng et al., 2017; IDF, 2021; Davies et al., 2022). The prevalence of T2DM, a major global public health issue, is on the rise (IDF, 2021). T2DM significantly impacts individuals' quality of life and financial stability (Gad et al., 2023). Therefore, it is crucial to comprehend the epidemiology of this disease and its impact on public health to effectively prevent and control its spread.

T2DM is a chronic metabolic disorder marked by persistently high blood glucose levels resulting from a combination of diminished insulin production, insulin resistance, or both (Hall et al., 2011; Levitt, 2008). The prevalence of T2DM has been steadily rising worldwide, affecting approximately 463 million individuals aged 20 to 79 in 2021 (IDF, 2021). The projected number is expected to reach around 700 million by 2045. The IDF (2021) reported that the majority of diabetes cases were found in low- and middle-income countries, posing a double burden of communicable and non-communicable diseases in these countries, particularly in Africa.

T2DM has notable public health implications, including increased rates of cardiovascular disease, renal failure, blindness, and lower limb amputations (ADA, 2021). It is linked to higher healthcare costs, as well as a reduced quality of life (Trikkalinou et al., 2017). According to the IDF (2021) globally, the cost of the disease was estimated to be $760

billion, with about 50% of the financial burden borne by low- and middle-income countries. Prompt identification and effective management of the disease is crucial to minimize complications and optimize outcomes. Medication, including metformin and insulin, and regular blood glucose testing are essential components of optimal care for managing T2DM (Shaw et al., 2010; ADA, 2021). Understanding the epidemiology of the disease, and its impact on individuals and communities cannot be over-emphasized (Atun et al., 2017; ADA, 2021; IDF, 2021).

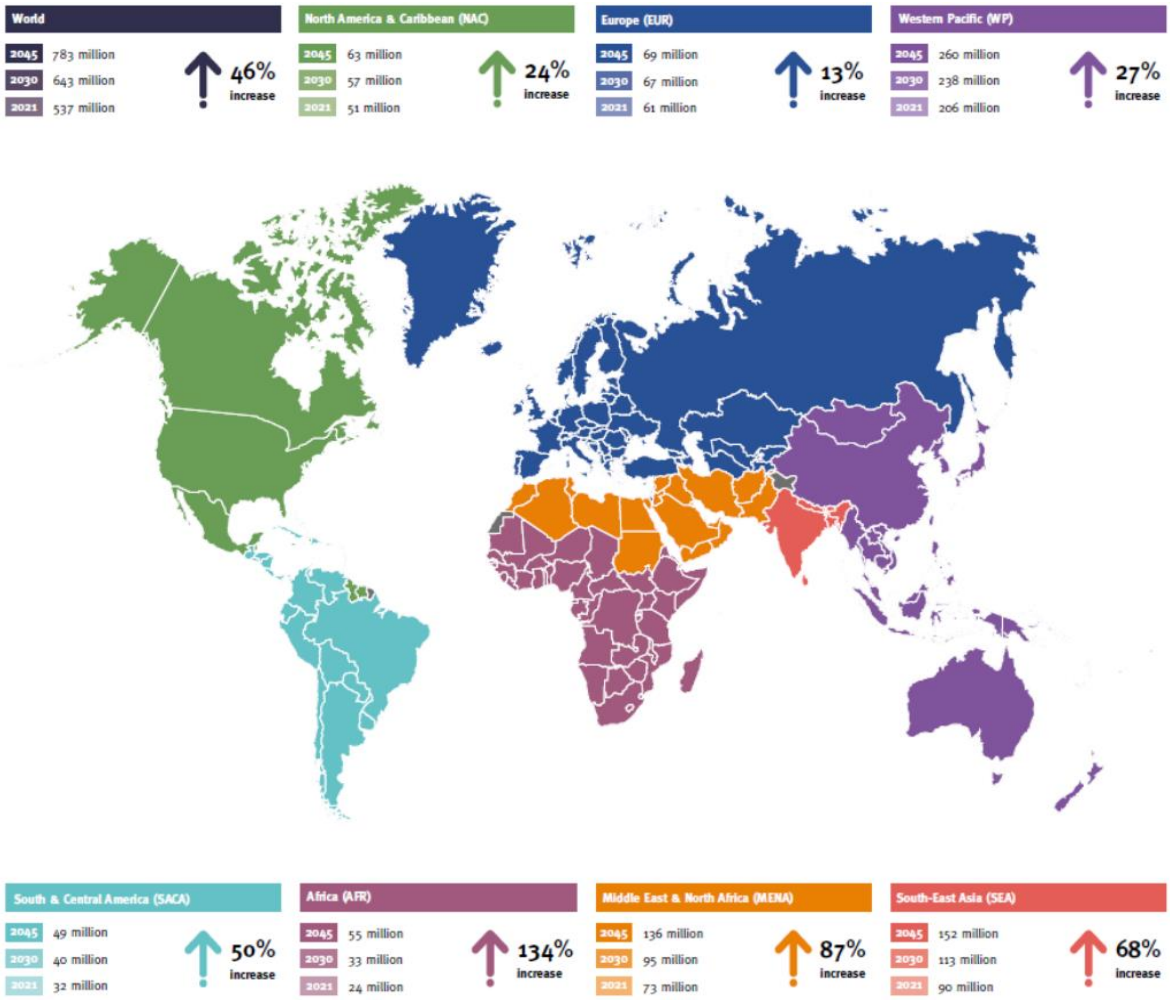

Figure 2.1: Number of Diabetics Globally and per IDF Region in 2021-2045 (20-79 years)

2.2 T2DM Prevalence in Ghana and Sub-Saharan Africa

Diabetes mellitus is a notable public health concern in Ghana and other sub-Saharan African (SSA) nations (Asamoah-Boaheng et al., 2019; NCD Risk Factor Collaboration [NCD-RisC], 2016; Lu et al., 2016; Stephani et al., 2018; IDF 2019; Sarkodie, 2019; IDF, 2021; Gad et al., 2023; GBD 2021 Diabetes Collaborators, 2023). According to the 2019 International Diabetes Federation (IDF) study, the prevalence of diabetes in Africa was 3.8% among adults, affecting a total of 19.4 million individuals (IDF, 2019). The Ministry of Health in 2012 estimated the prevalence of diabetes to be rising in Ghana (Ministry of Health, 2014; Zakariah, 2016; Ministry of Health, 2012) and it was reported to be higher in urban areas (10.4%) compared to rural areas (3.3%). Agyemang et al. (2016) found the prevalence of T2DM to be higher among urban men (10.3%) compared to women (9.2%). However, a much higher prevalence of undiagnosed type 2 diabetes has been reported (Issah et al., 2022).

The International Diabetes Federation (IDF, 2021) predicts a 24% rise in the prevalence of diabetes in sub-Saharan Africa by 2045. The estimated increase in the number of individuals with diabetes is projected to reach 63 million, compared to 51 million in 2021 (IDF, 2021). A previous report by the IDF projected the highest prevalence of diabetes to be among individuals aged 45 to 64 (IDF, 2019). The IDF (2019) also predicted a substantial increase in the number of adults with diabetes in Ghana. Globally, the disease was projected to reach 3.4 million, indicating a 98% rise from the recorded figure of 1.7 million in 2019 (IDF, 2019; IDF, 2021). An intriguing aspect of this trend is that the disease is emerging in a region already plagued with high rates of communicable diseases (Hall et al., 2011). Furthermore, the region has the highest proportion of undiagnosed T2DM: more than two-thirds of diabetics are unaware of their condition (Goedecke et al., 2017). T2DM prevalence rises

with age, increasing more in urban areas (58.8 percent) and more in women than in men (Goedecke et al., 2017; IDF, 2019).

Diabetes is linked to various microvascular complications (such as retinopathy, nephropathy, and neuropathy) and macrovascular complications (including cardiovascular diseases) (Deshpande et al., 2008; Hall et al., 2011). These complications substantially increase the overall risk of morbidity, disability, reduced quality of life, and premature death (Atun et al., 2017; Davies et al., 2022; Lamptey et al., 2022). Therefore, the disease can significantly impact the individual's life expectancy (Tachkov et al., 2020). Hyperglycemia can result in serious complications, including diabetic ketoacidosis (DKA) in individuals with Type 1 and T2DM, and hyperosmolar coma in patients with T2DM (Trikkalinou et al., 2017; Tachkov et al., 2020; ADA, 2021). Hypoglycemia can occur in patients on hypoglycemic-prone agents and may lead to seizures or loss of consciousness (ADA, 2015; ADA, 2018; ADA, 2019). Diabetes can affect all organs in the body (IDF, 2015; Daryabor et al., 2020). It has a substantial impact on multiple organs, leading to various health conditions including blindness, kidney failure, heart disease, stroke, amputations, dementia, infertility, nerve damage, and pregnancy complications (Hall et al., 2011; IDF, 2015). The IDF (2021) estimated the financial consequences of diabetes to comprise expenses incurred by individuals with diabetes, as well as private or public payers and governments. Global health expenditure related to diabetes has experienced a significant rise, increasing from US $232 billion in 2007 to US $966 billion in 2021 for individuals between the ages of 20 and 79. This represents a substantial (316%) increase over 15 years. The global economic burden of the disease, including its complications significantly affects individuals with the disease, their families, and national economies (Assah & Mbanya, 2009; Bommer et al., 2018; Mercer et al., 2019).

The current rise in chronic non-communicable diseases (NCDs) in sub-Saharan Africa (SSA) can be attributed to several factors, including urbanization, economic growth, lifestyle changes (epidemiological transition) (Assah & Mbanya, 2009; Peer et al., 2014; Atiim & Elliott, 2016). The management of diabetes mellitus in the SSA region is made more difficult by factors such as low awareness, limited access to healthcare, insufficient resources, and inadequate healthcare systems (Foma et al., 2013).

2.3 Diagnosis and Prognosis of Diabetes

According to recommendations from the IDF and the ADA, the diagnosis of T2DM is based on blood glucose readings (ADA, 2021; IDF, 2021). Hyperglycemia, characterized by elevated fasting plasma glucose (FPG) levels of ≥126 mg/dL (7.0 mmol/L) or 2-hour postprandial plasma glucose (2h PG) levels of ≥200 mg/dL (11.1 mmol/L) following a 75g glucose load during an oral glucose tolerance test (OGTT), serves as the diagnostic criterion for T2DM (ADA, 2021; IDF, 2021). According to the ADA (2021), a diagnosis can be made using HbA1c level and when HbA1c levels are ≥6.5% (48 mmol/mol). The HbA1c test is a useful diagnostic and monitoring tool since it provides an average blood glucose reading for the previous two to three months.

Various screening techniques have been developed to identify individuals at high risk for T2DM. The Finnish Diabetes Risk Score (FINDRISC) is one of the commonly employed tools that assesses various factors including age, waist circumference, physical activity, family history of diabetes, and history of hypertension (Abdallah et al., 2020; Mugume et al., 2023). Values for the Diabetes Risk Score ranged from 0 to 20 (Lindstrom & Tuomilehto, 2003) and they recommended a score value of ≥9 with a sensitivity value of 0.78 and 0.81,

specificity of 0.77 and 0.76, and positive predictive values of 0.13 and 0.05 to indicate drug-treated diabetes.

The prognosis of individuals with T2DM exhibits variability and it is largely influenced by various factors, such as glycemic management, the presence of comorbidities, and complications (ADA, 2021). The extent to which an individual mitigates their risk of complications varies. Premature mortality can occur as a consequence of heart attack, stroke, and kidney disease. Disabilities such as blindness, amputation, heart disease, stroke, and nerve damage may be present. Individuals with T2DM may develop kidney failure, leading to a reliance on dialysis treatments or a need for kidney transplants.

Comorbidities, specifically cardiovascular diseases (CVDs), play a crucial role in determining the prognosis of T2DM (Sherwani et al., 2016; American Diabetes Association Professional Practice Committee., 2022). Patients with T2DM have an increased risk of developing CVD. Obesity, dyslipidemia, and hypertension commonly accompany T2DM and worsen its consequences (ADA, 2021). Diet and lifestyle factors, including physical activity, are important indicators of prognosis in individuals with T2DM. Regular exercise has been shown to improve glycemic control, and insulin sensitivity, reduce the risk of cardiovascular disease, and enhance quality of life in individuals with T2DM (Colberg et al., 2016). In addition, individuals with T2DM can improve glycemic control and reduce their risk of cardiovascular disease by consuming a nutritious diet that is low in added sugars, salt, saturated fats, and Trans-fats (Evert et al., 2014; ADA, 2021).

Thus, several factors, including hyperglycemia, coexisting conditions, the use of pharmaceutical therapy, and lifestyle choices, influence the diagnosis and prognosis of T2DM (Evert et al., 2014; Foma et al., 2013; American Diabetes Association Professional

Practice Committee., 2022; Colberg et al., 2016; Sherwani et al., 2016; Mercer et al., 2019). It is crucial to adopt a proactive approach in managing these factors in order to enhance outcomes for individuals with this chronic illness.

2.4 Economic Burden of T2DM

The economic burden of diabetes in Africa present specific characteristics aligning with the continent's varying economic environments, common limitations in health systems, as well as the epidemiological patterns relevant for the condition. While aggregate expenditure can be lower compared with high-income countries, the burden involved, including its impact on health systems as well as for households, can be significant considering limited health system budgets in many African nations (Mapa-Tassou et al., 2019).

A comprehensive examination of the cost of diabetes in the WHO African Region, conducted by Kirigia et al. (2009) provides critical information on the regional-level financial impact. It reveals that in the year 2000, the 7.02 million persons with diabetes in the WHO African Region accounted for a total cost in terms of economic loss equating $25.51 billion, based on purchasing power parity (Kirigia et al., 2009). Such a huge cost clearly shows that, despite the very low per capita expenditure on health in the region, the absolute cost in terms of economics for diabetes is still significant.

Distribution of the cost of the economies among different income groups in the African continent reveals an interesting pattern. Those with a Gross National Income (GNI) per capita above $8,000 accounted for about 43.65% of the total cost, though accounting for a small percentage of the people in the region. Middle-income nations, with a GNI between $2,000 and $7,999, only contributed a marginal 10.03%, while low-income nations, with a GNI less than $2,000, shared a whopping 46.32% (Kirigia et al., 2009).

The gaps are also emphasized through the comparison when considering economic loss per case for diabetes over a period of a year. In regional high-income countries, the average annual economic loss for each case for diabetes stood at $11,431.6, compared with $4,770.6 for middle-income nations, and $2,144.3 for low-income countries (Kirigia et al., 2009). Such variations are an outcome of the variations in expenditure towards health, standard remuneration, and treatment approach in different contexts.

National studies provide significant information for cost distribution in a whole continent. In Nigeria the direct cost every year connected with diabetes has been approximated to be in the range between $1.071 billion to $1.639 billion, reflecting a significant burden on the country's health system (Mapa-Tassou et al., 2019). This assessment highlights the significant cost incurred from major African nations with massive populations hit with the condition. In Cameroon, the total direct monthly cost for each diabetic individual is $148, a significant financial burden for many families in the country (Mapa-Tassou et al., 2019). Based on an annual perspective, the cost for dealing with diabetes amounts to an average figure of $1,776 for every individual over a year, a significant figure in comparison with the average income for a household in the country. Sudan offers an interesting case relative to the cost burdens imposed by diabetes in an economically challenged environment in Africa. In one specific appraisal, the direct yearly cost for treating type 2 diabetes stood at $175, including only medication cost and outpatient fees (Mapa-Tassou et al., 2019). Even though modest when contrasted with cost in wealthier nations, the cost, however, represents a significant financial burden for many Sudanese families, a cost again unaccounted for a variety of key cost drivers, including treatment for resultant complications and indirect cost.

Ghana offers a perfect case for assessing the economic features surrounding diabetes in a West African country. Kazibwe et al. (2024) in a systematic scoping review covering every facet, explored the epidemiological dimensions as well as relevant expenditure surrounding diabetes in Ghana, providing much-needed information on financial consequences surrounding diabetes treatment in an African lower-middle-income country (Kazibwe et al., 2024). The study found that the mean annual financial cost of managing one diabetic case at the outpatient clinic was estimated at GHc540.35, equivalent to 2021 $194.09 (Kazibwe et al., 2024). This figure represents direct medical costs for outpatient care and provides a baseline estimate for diabetes management costs in the Ghanaian healthcare system. However, this estimate likely underrepresents the total economic burden, as it excludes hospitalization costs, complications management, and indirect costs.

The relatively low cost per case in Ghana, compared with that seen in high-income countries, can be explained in part through reduced investment in health care, limited access to expensive treatments and technologies, and potentially less stringent management practice. However, measured against average income levels in Ghana, these expenditures are a significant economic burden for many households. The study also highlighted critical gaps in existing data for the economic cost borne by Ghana, including a lack of evidence for the overall economic cost in addition to prevalence cost for the regions (Kazibwe et al., 2024). It is a common deficiency among many African countries and a critical barrier in the effective allocation of resources, including health-based planning.

2.5 Clinical Management of T2DM: Core Components

The clinical management of T2DM is a complex task that involves various elements to achieve optimal glycemic regulation and prevent complications (IDF, 2015; Powers et al.,

2015; Freeman et al., 2018). This review provides a concise overview of the essential aspects of clinical care for individuals with T2DM. To prevent long-term complications like cardiovascular disease, neuropathy, and nephropathy, it is crucial to achieve and maintain optimal glycemic control. The effective management of T2DM requires lifestyle changes, including dietary modifications, physical activity, and weight regulation (Evert et al., 2014; Colberg et al., 2016; Mikhael et al., 2020; American Diabetes Association Professional Practice Committee, 2022). These modifications have benefits for patients by improving their quality of life, reducing cardiovascular risk factors, and optimizing glycemic control (ADA, 2021). Modifying one's diet to a low-carb or Mediterranean style can help with glycemic management and cardiovascular health. Intense lifestyle modification has been shown by the Diabetes Prevention Programme (DPP) to lower the occurrence of type 2 diabetes in high-risk patients (Evert et al., 2014; Galaviz et al., 2015; Martín-Peláez et al., 2020). Exercise can enhance glycemic control and increase insulin sensitivity (Colberg et al., 2016). Weight reduction has been demonstrated to effectively reduce cardiovascular risk factors and improve glycemic control in overweight or obese individuals (Wing et al., 2011; Boye et al., 2021). According to the ADA (2021), it is crucial to implement therapeutic interventions to optimize glycemic regulation, mitigate insulin resistance, and reduce the potential hazards associated with T2DM.Pharmaceutical interventions are essential for effectively managing T2DM and enhancing long-term results (Nogueira et al., 2020; Pousinho et al., 2020). Metformin, sulfonylureas, thiazolidinediones, dipeptidyl peptidase-4 inhibitors, glucagon-like peptide-1 receptor agonists, insulin, and sodium-glucose cotransporter-2 inhibitors are pharmacological classes used for glycemic management. The selection of a pharmaceutical agent is influenced by patient-specific factors, such as comorbidities, advanced age, and the individual's medication tolerance (Feingold, 2022;

Pousinho et al., 2020). To achieve optimal glycemic control, combination therapy is often required. The selection process of the therapeutic approach should consider the unique attributes of the patient (ADA, 2021).

Regular monitoring of blood glucose levels is essential for evaluating glycemic regulation and making appropriate treatment adjustments (Freckmann, 2020; Weinstock et al., 2020). Continuous glucose monitoring (CGM) devices provide real-time blood glucose data, which encourages patients to regularly monitor their blood glucose levels (Freckmann, 2020; Weinstock et al., 2020). Individuals can effectively carry out this task at home. Regular examination is necessary to evaluate long-term glycemic control by measuring HbA1c levels (Weinstock et al., 2020). Moreover, it is crucial to recognize that individuals with T2DM have an increased vulnerability to developing cardiovascular diseases (Einarson et al., 2018). Regular monitoring and assessment of blood pressure and lipid profiles are essential to prevent and manage the negative consequences associated with diabetes (ADA, 2021). The use of continuous glucose monitoring (CGM) devices have been recommended (Einarson et al., 2018; Freckmann, 2020; Weinstock et al., 2020; ADA, 2021).

Closely monitoring for potential complications, including retinopathy, nephropathy, and neuropathy, through regular diagnostic assessments is also recommended (Shrivastav et al., 2018). Prompt identification and timely intervention are crucial for reducing the potential for long-term illness and death (ADA, 2021). There is also an increasing likelihood of cardiovascular disease occurring in individuals with T2DM. To reduce the risk of cardiovascular complications, it is crucial to prioritize blood pressure regulation, cholesterol level management, and the use of antiplatelet medication (Shrivastav et al., 2018; Freckmann, 2020; Nogueira et al., 2020; Weinstock et al., 2020). Statins, known for their

effectiveness in managing lipid levels, have become the leading therapeutic approach. Individuals with a higher risk of cardiovascular complications should undergo a thorough evaluation for potential antiplatelet therapy (ADA, 2021).

Hence, the adoption of a multimodal approach is crucial for the effective management of T2DM (Sudlow et al., 2019; Maraş & Sürme, 2022). This approach includes implementing dietary modifications, using pharmaceutical interventions, closely monitoring blood glucose levels and potential complications, mitigating cardiovascular risks, and promptly identifying and addressing emerging complications (Maraş & Sürme, 2022). Managing T2DM effectively can improve glycemic control, reduce cardiovascular risk factors, and enhance patients' overall quality of life (Powers et al., 2015). To optimize outcomes, healthcare providers must engage in collaborative partnerships with patients. This involves jointly developing customized management protocols that consider the unique requirements and preferences of individuals.

Figure 2.2 displays the diabetes management zones as outlined by Coleman & Newton in their influential 2005 publication. Indications and symptoms related to disease control measures are categorized using a tripartite system in clinical settings. This system uses the colours green, yellow, and red to represent different classifications. The colour green is associated with equilibrium and the capacity to effectively manage illnesses. In contrast, the colour yellow symbolizes the importance of exercising caution and following recommended protocols to regain control. The colour red signifies a medical emergency that requires urgent attention and the expertise of a qualified professional. The physician acts as a facilitator in prescribing personalized therapeutic goals for glycemic regulation, considering the individual risk and benefit assessment of each patient (Coleman & Newton, 2005).

Individuals with diabetes should aim to keep their HbA1c levels below 6.5% (equivalent to 48 mmol/mol) as a therapeutic goal, particularly for those with an early and uncomplicated condition (Schmieder et al., 2018). While it is advisable to negotiate a specific target HbA1c, a value approaching 7% (53 mmol/mol) appears to be a satisfactory compromise for the majority of individuals diagnosed with type 2 diabetes. Extremely strict glycemic control is linked to heightened dangers, including hypoglycemia, weight gain, and potentially an increased mortality risk, especially in those who have had diabetes for a prolonged duration and are at increased cardiovascular risk and may be especially vulnerable to the negative effects of intensive control (Coleman & Newton, 2005; Schmieder et al., 2018; ADA, 2019; ADA, 2021).

Green Zone: Great Control	Green Zone Means
Current HbA1c: …… • Average blood sugars typically under 150 mg/dL • Most fasting blood sugars under 130 mg/dL • 2 hours after eating less than 180 mg/dL • Bedtime blood sugar is between 100 – 140 mg/dL • Blood pressure is less than 140/80 • Able to follow meal plan	• Blood sugars are under control • Continue taking medications as ordered • Continue routine blood glucose monitoring • Follow healthy eating habits • Keep all physician appointments
Yellow Zone: Caution	**Yellow Zone Means**
• HbA1c >8% • Average blood sugar between 150-210 mg/dL • Most fasting blood sugars under 180mg/dL • Two or more low blood sugars less than 70 mg/dL in the past week • Most blood sugars 2 hours after eating greater than 180 mg/dL • Bedtime blood sugar is less than 100 or greater than 150 mg/dL • Blood pressure is greater than 140/80 • Inadequate medication or supplies to care for diabetes • Eating <50% of their meals	• Blood sugars may indicate an adjustment of medications is needed • Increase physical activity level (At least 30 minutes a day of walking; if tolerated) • Call physician or provider if changes in activity level or eating habits don't improve blood sugar levels.
Red Zone: Stop and Think	**Red Zone Means**
• HbA1c greater than 10% • Average blood sugars are over 210 mg/dL • Most fasting blood sugars are well over 180mg/dL • Two or more low blood sugars less than 70 with difficulty returning it to normal zone in the past week. • Moderate or large ketones in urine • Nausea/vomiting or fruity breath • Blood pressure consistently > 140/80	*You need to see a doctor now.* Evaluation by a physician is urgent. Call physician to be seen that day or proceed to the emergency room.

Note: HbA1c levels given in percent; blood sugar levels given in mg per dL (150 mg per dL = 8.3 mmol per L; 200 mg per dL = 11.1 mmol per L; 210 mg per dL = 11.7 mmol per L).

Figure 2.2: Diabetes Zones for Management: A Stoplight Tool

2.6 Structured Educational Interventions in T2DM Cares

Structured educational interventions are foundational components of effective diabetes care, designed to systematically impart knowledge, develop self-management skills, and empower individuals with T2DM to engage actively in managing their condition (Sayuti, Malini and Lenggogeni, 2024). These programmes are typically evidence-based, follow a defined

curriculum, and are delivered by trained healthcare professionals, such as diabetes educators, dietitians, nurses, and pharmacists.

Structured Diabetes Self-Management Education and Support (DSMES) programmes have demonstrated consistent benefits in improving glycemic control, self-care behaviours, and psychosocial outcomes (Powers et al., 2015). According to the American Diabetes Association (ADA), DSMES should be offered at diagnosis, annually thereafter, during significant life transitions, and when there are changes in health status (ADA, 2023). These structured programmes often address essential topics such as healthy eating, physical activity, medication adherence, blood glucose monitoring, problem-solving, coping strategies, and risk reduction (Ernawati, Wihastuti and Utami, 2021; Dailah, 2024).

Recent systematic reviews affirm the effectiveness of structured educational interventions in reducing HbA1c (Chrvala, Sherr and Lipman, 2016; Emara et al., 2021; Lamptey et al., 2022; Chowdhury et al., 2024). For instance, Odgers-Jewell et al. (2017) reported that DSMES interventions delivered over a duration of more than six months were associated with a mean HbA1c reduction of approximately 0.6% in adults with T2DM. A systematic review by Chrvala et al. (2016) found that structured DSME significantly reduced HbA1c levels, with an average reduction of 0.74%. The effectiveness of DSME is enhanced when programmes are culturally tailored, involve family members, and include follow-up support (Attridge et al., 2014; Lamptey et al., 2022). These improvements are clinically significant and contribute to the prevention of diabetes-related complications.

Importantly, the structure and mode of delivery influence the outcomes of educational programs. Group-based education has been found to be as effective as individual sessions, with added benefits of improved family interaction, knowledge and understanding,

confidence, and motivation to manage the disease (Sawtell et al., 2015). Moreover, hybrid approaches that combine face-to-face sessions with digital modules or remote coaching have gained traction for their scalability and adaptability to diverse settings (Tourkmani et al., 2024). Tailoring structured interventions to the cultural, linguistic, and socioeconomic context of patients also improves engagement and outcomes (Attridge et al., 2014). A study by Franz et al. (2015) found that culturally adapted DSMES programmes achieved greater HbA1c improvements among ethnic minority groups compared to standard programs, underscoring the importance of cultural relevance in structured education.

To sustain the benefits of DSMES, reinforcement through ongoing follow-up and booster sessions is essential. Studies have shown that while initial improvements in glycemic control may wane over time without reinforcement, programmes that include continuous support maintain better long-term outcomes (Nooseisai et al., 2021; Cruz-Cobo, 2020). cardiovascular disease, neuropathy, and nephropathy, it is crucial to achieve and maintain optimal glycemic control.

2.7 Determinants of Glycemic Control in T2DM Patients

Type 2 diabetes mellitus (T2DM) is a progressive and chronic metabolic disease characterized by insulin resistance, impaired insulin secretion, and persistent hyperglycemia (ADA, 2023; IDF, 2021). T2DM accounts for over 90% of all diabetics worldwide and poses a serious public health issue due to its increasing prevalence, associated morbidity, and financial burden (IDF, 2021). The International Diabetes Federation (IDF, 2023) estimates that over 530 million people have diabetes today, and this figure will rise exponentially over the coming decades. In the sub-Saharan African region, and Ghana, T2DM is on the rise at a rapid rate due to urbanization, lifestyle changes, and limited access to quality healthcare

services (Pastakia et al., 2017; Zimmermann et al., 2018).Maintenance and attainment of optimal glycemic control, as conventionally assessed through glycated hemoglobin (HbA1c) levels, is important in preventing acute complications and postponing the development of long-term microvascular and macrovascular complications (ADA, 2023; American Diabetes Association Professional Practice Committee, 2022; Handelsman et al., 2015). Despite pharmacologic breakthroughs and clinical guidelines, a substantial percentage of patients with Type 2 Diabetes Mellitus (T2DM) fall short of recommended glycemic levels (Pastakia et al., 2017). This persistent failure underscores the need to act on not only clinical and physiological determinants but also behavioral, psychosocial, and system determinants of diabetes care.

Glycemic control is determined by a complex interplay of patient factors, healthcare team interactions, and broader social and environmental determinants (Adjei et al., 2024). Despite the pharmacologic cornerstone of glycemic control, patient activation in self-care, decision-making, and therapeutic relationships has been increasingly acknowledged as important. Emerging evidence informs the necessity to acknowledge and address the multifactorial determinants of patient behaviors and outcomes.

This review systematically discusses seven key determinants—as encapsulate in the social cognitive theory—of glycemic control in adults with T2DM. These seven key determinants of glycemic control are: diabetic knowledge, patient involvement in treatment decision-making, decision-making self-efficacy, satisfaction with care, social support (specifically from providers), provider communication style, and diabetes self-management behaviors. The determinants were selected because of their frequency in recent literature, modifiability, and potential for inclusion in person-centered models of diabetes care.

By synthesizing evidence derived from experimental studies, systematic reviews, meta-analyses, among others published in recent years, this review seeks to clarify the mechanisms by which these determinants influence glycemia and inform evidence-based targeted interventions. Priority is assigned to findings of interest to low- and middle-income countries, where health systems have additional challenges to contend with in addressing the epidemic of diabetes. The primary objective is to present a thorough and current conceptualization of the behavioral and psychosocial aspects of glycemic control and thereby provide evidence for researchers, clinicians, and policymakers striving to improve diabetes care and outcomes globally.

2.8 Personal Factors

Personal factors are individual characteristics that influence behavior, including knowledge, beliefs, attitudes, and self-perceptions. In the context of diabetes management, several personal factors have been identified as critical determinants of health outcomes. This section reviewed the literature on four key personal factors—patient involvement in treatment decision-making, diabetes knowledge, decision-making self-efficacy, and satisfaction with care—that has been acknowledged to influence health behaviours.

2.8.1 Patient Involvement in Treatment Decision-Making

Patient involvement in treatment decision-making, also known as shared decision-making (SDM), is a collaborative process in which patients and their healthcare providers work together to make healthcare choices (Montori et al., 2023). The concept of patient involvement in treatment decision-making has evolved significantly over the past three decades, moving beyond simple patient education to encompass comprehensive approaches that empower individuals to take active roles in their care (Snyder & Engström, 2016). The

importance of patient involvement in diabetes care cannot be overstated. Research consistently demonstrates that patients who actively participate in treatment decisions and possess adequate self-management skills achieve better glycemic control, experience fewer complications, and report a higher quality of life (Gómez-Velasco, et al., 2019). This approach respects patient preferences and values, and it has been shown to improve health outcomes in various chronic conditions, including diabetes.

Recent systematic reviews and meta-analyses have provided strong evidence for the effectiveness of SDM in diabetes care. For example, a 2025 systematic review by Al-Jumaili et al. found that interventions to improve SDM significantly improved glycemic control, with a mean reduction in HbA1c of 0.14% (Al-Jumaili et al., 2025). The review also found that SDM was associated with improved patient satisfaction and self-management behaviors. Another meta-analysis by Geta et al. (2024) found that interventions to improve SDM were particularly effective in patients with poorly controlled diabetes, with a greater reduction in HbA1c in this subgroup. The findings indicate that patient involvement in treatment decision-making is a critical component of effective diabetes care. The process helps in empowering patients to take an active role in their own health, which consequently can lead to improved glycemic control, greater satisfaction with care, and enhanced self-management behaviours. The review also found that patients generally preferred to be involved in treatment decisions, particularly regarding medication choices and lifestyle modifications. Geta et al. (2024) conducted a meta-analysis of randomized controlled trials examining the effectiveness of SDM interventions on glycemic control in diabetes patients. The meta-analysis included 15 studies with a total of 2,847 participants and found that SDM interventions resulted in a statistically significant reduction in HbA1c levels, with a mean difference of -0.14% (95% CI: -0.25 to -0.03, $p = 0.01$). Importantly, the analysis revealed

that the effect was more pronounced in patients with poorly controlled diabetes (HbA1c > 8%), suggesting that SDM may be particularly beneficial to high-risk patients. The meta-analysis also examined secondary outcomes and found that SDM interventions were associated with improved patient satisfaction scores (standardized mean difference = 0.32, 95% CI: 0.15 to 0.49, $p < 0.001$) and enhanced diabetes self-management behaviours (standardized mean difference = 0.28, 95% CI: 0.12 to 0.44, $p = 0.001$). These findings indicate that the benefits of SDM extend beyond glycemic control to include improved patient experience and self-care behaviours. However, it also identified several barriers to SDM implementation, including time constraints, lack of provider training, and patient health literacy issues.

The effectiveness of SDM in diabetes care can be understood through the lens of Social Cognitive Theory. When patients are actively involved in treatment decisions, they develop a greater sense of self-efficacy and personal agency, which are key determinants of health behavior change according to SCT (Thojampa and Sarnkhaowkhom, 2019; Smith et al., 2020). The collaborative nature of SDM also provides social support from healthcare providers, which is another important component of the SCT framework (Resnicow et al., 2022). Furthermore, SDM interventions often include educational components that enhance patient knowledge and understanding of their condition (Powers et al., 2015). This increased knowledge, combined with the opportunity to express preferences and concerns, can lead to treatment plans that are more aligned with patient values and lifestyle, thereby improving adherence and outcomes (Hoffman & Glaszious, 2016; Powers et al., 2015). Ranjbar et al. (2024) study findings support the broader evidence that theory-based behavioral change educational interventions are highly effective, with research indicating that 90% of studies show overall improvement in diabetes self-management education and support (DSMES)

when based on theoretical frameworks (Ranjbar et al., 2024). This evidence suggests that structured educational interventions are most effective when they incorporate explicit behavioral change theories that address the cognitive and motivational factors underlying patient decision-making.

Despite the evidence for its effectiveness of structured educational interventions on SDM, the implementation of SDM in diabetes care faces several challenges. Al-Jumaili et al. (2025) identified time constraints as the most commonly reported barrier, with healthcare providers expressing concern about the additional time required for collaborative decision-making. Other barriers included lack of provider training in SDM techniques, patient health literacy issues, and organizational factors such as lack of institutional support. However, the review also identified several facilitators that can support SDM implementation. These included the use of decision aids and educational materials, provider training programs, and organizational changes such as longer appointment times and team-based care models. Al-Jumaili et al. (2025) emphasized that successful SDM implementation requires a multi-level approach that addresses individual, interpersonal, and organizational factors.

2.8.2 Knowledge of Diabetes

Patient Diabetes knowledge is a fundamental personal factor that influences self-management behaviours and health outcomes. Patients with better understanding of their condition, its complications, and management strategies are more likely to engage in appropriate self-care behaviours and achieve better glycemic control. This section reviewed evidence on the relationship between diabetes knowledge and health outcomes, as well as the effectiveness of educational interventions in improving knowledge and outcomes.

Recent research has provided compelling evidence for the relationship between diabetes knowledge and health outcomes. Alshammari et al. (2025) conducted a study among patients with type 2 diabetes in Saudi Arabia and found that 62.4% of participants had poor diabetes knowledge. The study used a validated diabetes knowledge questionnaire and found a significant inverse relationship between knowledge scores and HbA1c levels ($r = -0.34$, $p < 0.001$), indicating that patients with better knowledge had better glycemic control. The study also examined factors associated with diabetes knowledge and found that education level, duration of diabetes, and previous participation in diabetes education programmes were significant predictors of knowledge scores. Patients with higher education levels had significantly better knowledge scores (mean difference = 1.8 points, $p < 0.001$), and those who had participated in diabetes education programmes had better knowledge than those who had not (mean difference = 2.1 points, $p < 0.001$).

These findings are consistent with the broader literature on diabetes knowledge and outcomes (Alemayehu et al., 2020; Shawahna et al., 2021). Hildebrand et al. (2020), Ernawati et al. (2021), and Esferjani et al. (2022) found that individuals with a greater understanding of diabetes and its care process had better glycemic control compared to those with less knowledge. The inverse relationship between knowledge and HbA1c suggests that educational interventions that improve patient knowledge may lead to better glycemic control. However, the relationship between knowledge and outcomes is complex and may be mediated by other factors such as self-efficacy and self-management behaviors.

The effectiveness of educational interventions in improving diabetes knowledge has been demonstrated in several recent studies. Ayuso-Diaz et al. (2025) conducted a pre-post study examining the effectiveness of a nurse-led educational intervention on diabetes knowledge

in 150 patients with type 2 diabetes. The intervention consisted of four 90-minute group sessions delivered over 8 weeks and covered topics such as diabetes pathophysiology, medication management, nutrition, and self-monitoring. The study found significant improvements in diabetes knowledge scores from baseline to post-intervention (mean increase = 3.2 points, 95% CI: 2.8 to 3.6, $p < 0.001$). The improvement was sustained at 3-month follow-up (mean increase = 2.9 points, 95% CI: 2.5 to 3.3, $p < 0.001$), suggesting that the educational intervention had lasting effects on patient knowledge. The study also examined the impact of the intervention on self-care behaviors and found significant improvements in several domains, including dietary adherence ($p = 0.002$), blood glucose monitoring ($p < 0.001$), and foot care ($p = 0.01$). However, the study did not find significant improvements in HbA1c levels, which the authors attributed to the relatively short follow-up period and the need for longer-term behavioral changes to translate into glycemic improvements.

Structured diabetes education programmes have been developed and evaluated in various healthcare settings. These programmes typically follow a standardized curriculum and are delivered by trained healthcare professionals (Funnell et al, 2009; Gillett et al., 2010). The evidence for the effectiveness of structured education programmes is mixed, with some studies showing significant improvements in knowledge and outcomes, while others show more modest effects (Coates et al., 2013; Norbert et al., 2019). The variability in effectiveness may be related to differences in programme content, delivery methods, participant characteristics, and follow-up duration (NICE, 2025). Programmes that are more intensive, longer in duration, and include ongoing support may be more effective than brief, one-time interventions (Coates et al., 2013; Lamptey et al., 2022; NICE, 2025). Additionally,

programmes that are tailored to specific patient populations or cultural contexts may be more effective than generic programs.

Despite the evidence for the importance of diabetes knowledge, several gaps remain in our understanding of this relationship. First, most studies have used cross-sectional designs, which limit our ability to establish causal relationships between knowledge and outcomes (Solem, 2015; Wang & Cheng, 2020). Longitudinal studies are needed to better understand how changes in knowledge over time relate to changes in self-management behaviors and health outcomes.

Second, there is limited research on the optimal content and delivery methods for diabetes education programs. While many programmes cover similar topics, there is little evidence on which specific components are most important for improving knowledge and outcomes. Future research should examine the effectiveness of different educational approaches and identify the key components of successful programs.

Finally, there is a need for research on how to sustain knowledge improvements over time. Many studies show initial improvements in knowledge following educational interventions, but these improvements may decline over time without ongoing reinforcement. Research on maintenance strategies and long-term follow-up is needed to understand how to sustain the benefits of diabetes education.

2.8.3 Decision-Making Self-Efficacy

Decision-making self-efficacy refers to an individual's confidence in their ability to make informed decisions about their health and healthcare. In the context of diabetes management, this includes confidence in making decisions about medication adherence, dietary choices,

physical activity, and other self-management behaviors. Self-efficacy is a core construct in Social Cognitive Theory and has been consistently identified as a key predictor of health behavior change and outcomes.

Self-efficacy theory, developed by Albert Bandura (1986), posits that individuals' beliefs about their capabilities to perform behaviors necessary to produce specific performance attainments influence their motivation, affect, and actions. In diabetes management, self-efficacy encompasses multiple domains, including confidence in managing blood glucose levels, following dietary recommendations, engaging in physical activity, and managing diabetes-related stress (Ataya et al., 2024; Jihyon et al., 2025).

Recent research has provided strong evidence for the relationship between self-efficacy and diabetes outcomes (Ataya et al., 2024; Jihyon et al., 2025)). Mahmoud et al. (2024) conducted a comprehensive study examining the role of self-efficacy enhancement in improving self-management behaviors in patients with type 2 diabetes. The study used a validated self-efficacy scale and found that patients with higher self-efficacy scores had significantly better self-management behaviors across multiple domains.

The effectiveness of self-efficacy enhancement interventions has been demonstrated in several recent studies. Mahmoud et al. (2024) evaluated a structured education programme specifically designed to enhance self-efficacy in 200 patients with type 2 diabetes. The intervention consisted of six weekly group sessions that included goal setting, problem-solving training, and peer support activities designed to build confidence in diabetes self-management. The study found significant improvements in self-efficacy scores from baseline to post-intervention (mean increase = 12.5 points, 95% CI: 10.2 to 14.8, $p < 0.001$). More importantly, these improvements in self-efficacy were associated with significant

improvements in self-management behaviors, including dietary adherence ($p < 0.001$), physical activity ($p = 0.002$), and blood glucose monitoring ($p < 0.001$). The study also found a significant reduction in HbA1c levels at 6-month follow-up (mean reduction = 0.8%, 95% CI: 0.5 to 1.1, $p < 0.001$).

Jackson et al. (2025) conducted a cross-sectional study examining the relationship between diabetes management self-efficacy and glycemic control in 450 patients with type 2 diabetes. The study found a significant negative correlation between self-efficacy scores and HbA1c levels ($r = -0.42$, $p < 0.001$), indicating that patients with higher self-efficacy had better glycemic control. The study also found that self-efficacy was a significant predictor of fasting blood glucose levels ($\beta = -0.35$, $p < 0.001$) after controlling for demographic and clinical variables.

The mechanisms through which self-efficacy influences diabetes outcomes are well-established in the literature (Amer et al., 2018; Walker et al., 2014). According to Social Cognitive Theory, self-efficacy influences behavior through several pathways. First, individuals with higher self-efficacy are more likely to set challenging goals and persist in the face of obstacles. Second, self-efficacy influences the amount of effort individuals expend on health behaviors and their resilience when faced with setbacks. Third, self-efficacy affects emotional reactions to health challenges, with higher self-efficacy associated with lower anxiety and depression.

In the context of diabetes management, these mechanisms translate into more consistent self-management behaviors, better problem-solving when faced with challenges, and greater persistence in maintaining healthy lifestyle changes. The research by Mahmoud et al. (2024) provides evidence for these mechanisms, showing that improvements in self-efficacy were

associated with improvements in multiple self-management behaviors. Walker et al. (2014) found in their study that stronger self-efficacy was correlated with good glycemia control, medication compliance, self-care behavior and quality of mental health. They concluded that it is of relevance aiming at self-efficacy with educational intervention targeting at poor minority populations.

Several factors have been identified as important influences on diabetes self-efficacy. Jackson et al. (2025) found that education level, duration of diabetes, and previous participation in diabetes education programmes were significant predictors of self-efficacy scores. Patients with higher education levels had significantly higher self-efficacy scores (mean difference = 8.3 points, $p < 0.001$), and those with longer duration of diabetes had lower self-efficacy scores ($r = -0.28$, $p < 0.001$). The study also found that social support was a significant predictor of self-efficacy ($\beta = 0.31$, $p < 0.001$), highlighting the importance of environmental factors in supporting individual self-efficacy beliefs. This finding is consistent with Social Cognitive Theory, which emphasizes the reciprocal relationship between personal, environmental, and behavioral factors.

The evidence on decision-making self-efficacy has important implications for diabetes care practice. Healthcare providers need to assess patient self-efficacy as part of routine diabetes care and provide targeted interventions to enhance self-efficacy when needed. Self-efficacy enhancement strategies include goal setting, problem-solving training, skills building, and providing opportunities for mastery experiences. The research also suggests that self-efficacy interventions should be tailored to individual patient needs and characteristics (Ataya et al., 2024; Dineen-Griffin et al., 2019). Patients with lower education levels or longer duration of diabetes may need more intensive self-efficacy enhancement

interventions. Additionally, interventions should address both individual and environmental factors that influence self-efficacy, including social support and healthcare provider communication

2.8.4 Satisfaction with Care

Satisfaction with care is an important personal factor that reflects patients' perceptions of the quality and appropriateness of their healthcare experience. In diabetes management, satisfaction with care encompasses multiple dimensions, including satisfaction with provider communication, treatment effectiveness, accessibility of services, and overall care coordination (Alsubahi et al., 2025). Research has shown that higher satisfaction with care is associated with better adherence to treatment recommendations and improved health outcomes (Keelson et al., 2024).

Patient satisfaction is a multidimensional construct that reflects the degree to which healthcare services meet patient expectations and preferences. In diabetes care, satisfaction encompasses both technical aspects of care (such as clinical competence and treatment effectiveness) and interpersonal aspects (such as communication, empathy, and respect for patient preferences) (Akanyako, 2024; Adhikari et al., 2024; Manzoor et al., 2019). Recent research has provided evidence for the relationship between satisfaction with care and diabetes outcomes. Alharbi et al. (2025) conducted a study examining the association between patient-centered care and satisfaction among 380 diabetes patients. The study used validated measures of patient-centered care and patient satisfaction and found a strong positive correlation between these constructs ($r = 0.68$, $p < 0.001$).

The concept of patient-centered care has gained increasing attention in diabetes management. Patient-centered care is defined as care that is respectful of and responsive to

individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions (Muganzi et al., 2024). Alharbi et al. (2025) found that patients who received more patient-centered care reported significantly higher satisfaction scores across multiple domains. The study examined several dimensions of patient-centered care, including respect for patient preferences, coordination of care, information and communication, physical comfort, emotional support, and involvement of family and friends. All dimensions were significantly associated with patient satisfaction, with information and communication showing the strongest association ($\beta = 0.45$, $p < 0.001$). The study also found that patient satisfaction was significantly associated with self-management behaviors. Patients with higher satisfaction scores were more likely to adhere to medication regimens (OR = 2.3, 95% CI: 1.5 to 3.5, $p < 0.001$), follow dietary recommendations (OR = 1.8, 95% CI: 1.2 to 2.7, $p = 0.004$), and engage in regular blood glucose monitoring (OR = 2.1, 95% CI: 1.4 to 3.2, $p = 0.001$).

Several factors have been identified as important determinants of patient satisfaction in diabetes care. The research by Alharbi et al. (2025) found that provider communication skills, care coordination, and accessibility of services were the most important predictors of patient satisfaction. Patients who reported better communication with their healthcare providers had significantly higher satisfaction scores ($\beta = 0.52$, $p < 0.001$). The study also found that demographic and clinical factors influenced satisfaction levels. Older patients reported higher satisfaction scores than younger patients (mean difference = 3.2 points, $p = 0.02$), and patients with better glycemic control reported higher satisfaction ($r = 0.31$, $p < 0.001$). These findings suggest that satisfaction with care is influenced by both healthcare delivery factors and patient characteristics.

The relationship between satisfaction with care and health outcomes is complex and may be bidirectional. Patients who are more satisfied with their care may be more likely to adhere to treatment recommendations and engage in self-management behaviors, leading to better outcomes. Conversely, patients who achieve better outcomes may be more satisfied with their care (Muganzi et al., 2024; Prakash, 2010). The research by Alharbi et al. (2025) provides evidence for both pathways. The study found that satisfaction with care was significantly associated with better self-management behaviors, which in turn were associated with better glycemic control. However, the study also found that patients with better glycemic control reported higher satisfaction scores, suggesting a bidirectional relationship.

The evidence on satisfaction with care has important implications for quality improvement in diabetes care. Healthcare organizations should regularly assess patient satisfaction and use this information to identify areas for improvement. Particular attention should be paid to provider communication skills, care coordination, and accessibility of services, as these factors have been consistently identified as important determinants of satisfaction (ElSayd et al., 2023; Muganzi et al., 2024) or dissatisfaction (Dalal et al., 2020).

Various research also suggests that improving satisfaction with care may lead to better health outcomes through improved adherence and self-management behaviors (Prakash, 2010; Alodhialah et al., 2024). Therefore, efforts to improve patient satisfaction should be viewed not only as important for patient experience but also as a strategy for improving clinical outcomes.

2.9 Environmental Factors

Environmental factors are external influences that affect behavior and health outcomes. In the context of diabetes management, environmental factors include social support, healthcare system characteristics, and community resources. Social Cognitive Theory emphasizes the importance of environmental factors in shaping behavior and highlights the reciprocal relationship between personal, environmental, and behavioral factors (Bandura, 1986). This section reviewed the literature on two key environmental factors: social support received from providers and provider communication style.

2.9.1 Social Support Received from Providers

Social support from healthcare providers is a critical environmental factor that influences diabetes self-management and outcomes (Almubaid et al., 2024; Adu et al., 2024). Provider support encompasses both instrumental support (such as providing information and resources) and emotional support (such as empathy, encouragement, and validation) Almubaid et al., 2024; Pan & Ye, 2025). Research has consistently shown that patients who receive more social support from their healthcare providers have better self-management behaviors and health outcomes (Lin et al., 2025; Eton et al, 2017).

Social support theory suggests that support from others can influence health through several mechanisms, including direct effects on physiological processes, buffering effects on stress, and influences on health behaviors (Gallant, 2013). In the context of diabetes care, provider support can enhance patient self-efficacy, provide practical assistance with self-management tasks, and offer emotional encouragement during challenging times (Adu et al., 2024; Kerari, 2024; Powers et al., 2020).

Recent systematic review evidence has strengthened our understanding of the relationship between provider support and diabetes outcomes. Almubaid et al. (2024) conducted a comprehensive systematic review examining the impact of social support on health outcomes of diabetic patients. The review included 22 studies and found a significant correlation between social support and improved health outcomes in diabetes patients. Thus, Almubaid et al. (2024) study provided compelling evidence of the importance of provider support in diabetes care. The review found that most studies reported that social support improves health outcomes of diabetic patients, with provider support being identified as a key component alongside family and community support (Adu et al., 2024; Eton et al., 2017; Gallant, 2013; Kerari, 2024; Powers et al., 2020).

The review identified several mechanisms through which provider support influences outcomes. First, patient-provider relationships characterized by acceptance, collaboration, and warmth were associated with better diabetes management. Second, provider support was found to promote patient self-efficacy, which in turn increased patients' ability to manage their diabetes effectively. Third, adequate social support from providers was associated with better compliance with diabetes treatment and management protocols (Almubaid et al., 2024; Eton et al., 2017; Kerari, 2024). Again, several specific ways that provider support operates have been identified by Almubaid et al. (2024). External support from providers can promote patient self-efficacy, which increases the ability to manage type 2 diabetes. Patients with higher self-efficacy, supported by provider encouragement and guidance, are more capable of self-managing their diabetes effectively. The research also suggests that provider support influences health beliefs and locus of control. Patients who receive adequate social support from providers and have an internal health locus of control are more compliant with

continuing diabetes management. This finding highlights the importance of provider support in fostering patient autonomy and self-direction in diabetes care.

The literature identifies several types of support that providers can offer to diabetes patients. Instrumental support includes providing information about diabetes management, teaching self-care skills, and helping patients access resources and services. Emotional support includes showing empathy, providing encouragement, and validating patient experiences and concerns (Almubaid et al., 2024). They also found that different types of support may be more or less important depending on the context and patient needs. For example, families were found to provide more support with practical management tasks such as insulin administration, blood glucose monitoring, and healthy meal preparation, while friends provided more emotional support for "normalizing" the diabetes experience. However, healthcare providers play a unique role in providing both instrumental and emotional support. Providers have the clinical expertise to offer accurate information and guidance, while also being positioned to provide ongoing emotional support and encouragement throughout the course of diabetes management.

Despite the evidence for its importance, several barriers can limit the provision of social support by healthcare providers. Time constraints during clinical encounters are a commonly cited barrier, as providers may feel pressured to focus on clinical tasks rather than providing emotional support. Again, lack of training in communication and support skills may also limit providers' ability to offer effective social support. Moreover, organizational factors can also create barriers to provider support. Healthcare systems that emphasize efficiency and productivity may not provide adequate time or incentives for providers to engage in

supportive behaviors. Additionally, high patient loads and administrative burdens may limit providers' capacity to provide individualized support to patients.

2.9.2 Provider's Communication Styles

Provider communication style is another critical environmental factor that influences diabetes management and outcomes. Communication style encompasses both verbal and non-verbal behaviors that providers use when interacting with patients, including the tone of voice, body language, listening skills, and approach to information sharing (Sharkiya, 2023). Research has shown that provider communication style can significantly impact patient satisfaction, adherence to treatment recommendations, and health outcomes (Jones, 2024). Thus, effective communication is fundamental to the provider-patient relationship and is essential for successful diabetes management.

Communication serves multiple functions in healthcare, including information exchange, relationship building, and shared decision-making (Sharkiya, 20203). The style of communication used by providers can influence patient trust, understanding, and motivation to engage in self-management behaviors. Recent research has provided mixed findings regarding the relationship between provider communication style and diabetes outcomes. Alotaibi et al. (2024) conducted a study examining the impact of physician communication skills on glycemic control in 332 patients with diabetes. The study used the Communication Assessment Tool (CAT) to evaluate patient perceptions of physician communication skills and examined the relationship between communication scores and glycemic control. The study found high patient satisfaction with physician communication skills, with an overall percentage of excellent ratings of 75.3%. The percentage of excellent ratings for most questions varied between 70% and 80%, indicating generally positive patient perceptions of

provider communication. However, the study found no significant association between overall mean communication assessment scores and glycated hemoglobin levels or other metabolic features (except for diastolic blood pressure). This finding suggests that while patients may be satisfied with provider communication, this satisfaction does not necessarily translate directly into better glycemic control.

An examination of specific aspects of communication in the study found that the lowest percentage of excellent ratings was received for the question about involvement in decisions as much as patients wanted. This finding is consistent with other research showing that patients often desire more involvement in treatment decisions than they currently receive. These findings of Alotaibi et al. (2024) were contrary to what others have found—positive associations between provider communication and diabetes outcomes. White et al. (2015) also found no association between overall mean CAT scores and HbA1c levels after adjustment for confounders. However, White et al. (2015) did find that better communication was associated with higher medication adherence and treatment satisfaction.

Other studies cited by Alotaibi et al. have also found no association between patient satisfaction with physician communication and diabetes control, including studies by Al Shahrani and Baraja (2014) and Ahmed et al. (2016). These mixed findings suggest that the relationship between provider communication and diabetes outcomes is complex and may be influenced by other factors.

Several factors may explain the mixed findings regarding provider communication and diabetes outcomes. First, the overall high satisfaction with communication in the Alotaibi et al. (2024) study, combined with acceptable glycemic and metabolic control among participants, may have limited the ability to detect associations. In populations with greater

variation in communication quality or glycemic control, stronger associations might be observed. Second, other factors such as medication adherence and self-care behaviors may play significant role in diabetes control than patient satisfaction with communication alone. While communication satisfaction may not directly impact glycemic control, it may influence other important outcomes such as adherence and quality of life. Third, the relationship between communication and outcomes may be mediated by other factors such as patient self-efficacy, knowledge, and motivation. Effective communication may enhance these mediating factors, which in turn influence self-management behaviors and outcomes.

Despite the mixed findings regarding outcomes, research has identified several components of effective provider communication in diabetes care. These include active listening, empathy, clear information sharing, shared decision-making, and cultural sensitivity. Alotaibi et al. (2024) found that patients particularly valued providers who understood their health concerns, as better glycemic control may likely be associated with higher patient satisfaction with their physician's understanding of their values ad concerns.

2.10 Behavioural Factors

Behavioral factors are the actions and activities that individuals engage in that directly influence their health outcomes. In diabetes management, behavioral factors primarily encompass self-management behaviors, which include a range of activities that patients perform to manage their condition effectively (Ahmad & Joshi, 2023). Social Cognitive Theory emphasizes that behaviors are influenced by both personal and environmental factors and that successful behavior change requires attention to all three components of the theory. This section reviewed literature on diabetes self-management behaviors and their relationship to health outcomes.

2.10.1 Diabetes Self-Management Behaviors

Diabetes self-management behaviors are the daily activities that individuals with diabetes perform to manage their condition and prevent complications. These behaviors typically include blood glucose monitoring, medication adherence, dietary management, physical activity, and foot care (Ahmad & Joshi, 2023; Powers et al., 2015). Research has consistently shown that patients who engage in more frequent and appropriate self-management behaviors have better glycemic control and fewer diabetes-related complications (Powers et al., 2015; Powers et al., 2020; Ahmad & Joshi, 2023).

Self-management behaviors in diabetes are typically conceptualized as a multidimensional construct encompassing several key domains. The most commonly studied domains include glucose monitoring, dietary control, physical activity, medication adherence, and foot care (Powers et a., 2015). Each of these domains requires specific knowledge, skills, and motivation, and patients may perform better in some domains than others. Recent research has provided comprehensive evidence on the current state of diabetes self-management behaviors and their relationship to outcomes. Gu et al. (2025) studied 1,817 adults with type 2 diabetes in China to understand their self-management behaviors and glycemic control. The study found that the mean score of overall self-management behaviors was 5.89 on a 7-point scale, indicating suboptimal performance. Only 26.86% of participants reported good glycemic control, highlighting the challenges in achieving optimal diabetes management. The study examined five specific self-management behaviours and found significant variation in performance across domains.

The effectiveness of structured education programmes in improving self-management behaviors has been demonstrated in several recent studies. Scannell et al. (2025) conducted

a retrospective analysis of participants who attended the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) structured diabetes self-management education programme in Ireland. The study examined the impact of the programme on clinical outcomes at 6-month follow-up. The DESMOND programme was a 6-hour structured education programme delivered by registered dietitians in primary care settings. The study found that participants who completed the programme showed significant improvements in HbA1c levels, with a reduction of 6.45 mmol/mol ($p = 0.006$). The number of participants achieving the target HbA1c level below 53 mmol/mol increased from 52% at baseline to 71% at follow-up ($p < 0.001$). The study also found clinically significant improvements in weight and BMI. Participants had a mean weight reduction of 1.4 kg.

The effectiveness of self-management interventions can be understood through the lens of Social Cognitive Theory. According to SCT, behavior change occurs through the interaction of personal factors (such as knowledge and self-efficacy), environmental factors (such as social support and resources), and behavioral factors (such as skills and habits). Successful interventions typically address all three components of this model. The DESMOND programme evaluated by Scannell et al. (2025) incorporates several SCT principles. The programme provided education to enhance knowledge (personal factor), delivered in a group setting that provides peer support (environmental factor), and includes practical skills training (behavioral factor). The combination of these elements may have explained the program's effectiveness in improving outcomes. Gu et al. (2025) also provided insights into the mechanisms of self-management behavior change. The finding that dietary control had the greatest impact on glycemic control suggests that interventions focusing on nutrition education and behavior change may be particularly effective. However, the study also found

that glucose monitoring had the lowest performance scores, suggesting that interventions to improve monitoring behaviors are also needed.

Despite the evidence demonstrating the importance of self-management behaviors, many patients struggle to maintain optimal self-care practices. The research by Gu et al. (2025) suggests that self-management behaviors and glycemic control remain suboptimal in many populations. Several factors may contribute to these challenges, including lack of knowledge, low self-efficacy, limited social support, financial constraints, and competing life priorities. The study's finding that certain populations (younger persons, rural persons, and those with financial difficulties) benefit less from self-management suggests that barriers may be particularly pronounced in these groups. Addressing these barriers may require targeted interventions that are tailored to the specific needs and circumstances of individuals and different populations.

2.11 Effects of the Determinants on Glycemic Control in T2DM

A growing body of evidence over the past decade has consistently affirmed that several psychosocial and behavioral determinants significantly influence HbA1c levels, the gold-standard biomarker for long-term glycemic control in patients with T2DM. The distilled findings from literature reviewed on the impact of key determinants on glycemic control are presented below.

Improved diabetes knowledge enables patients to make informed decisions regarding diet, medication adherence, glucose monitoring, and risk reduction. Studies show that patients with higher diabetes knowledge and understanding are significantly more likely to maintain HbA1c within target levels. For example, Chen et al. (2020) found that structured diabetes

education reduced HbA1c by approximately 0.6% over six months, while patients with low knowledge had poor glycemic profiles and limited self-management capacity.

Active involvement in treatment-related decisions enhances patient autonomy and motivation, which translates into improved adherence and glycemic control. Geta et al. (2024) found that shared decision-making interventions significantly decreased the level of HbA1c by 0.14% (95% CI = -0.28, -0.01, P = 0.00) when made in person or face-to-face at the point of care.

Decision-making self-efficacy, or the confidence to make informed diabetes care choices, is closely tied to behavior execution. Higher self-efficacy levels have been shown to predict stronger engagement in diet regulation, medication use, and glucose monitoring—key behaviors linked to HbA1c improvement. Studies such as Babak et al. (2022) highlight that patients with high self-efficacy effectively improved metabolic control in patients with type 2 diabetes, especially when combined with targeted behavioral interventions.

Patient satisfaction with diabetes care services correlates with better medication adherence and clinic attendance, which support tighter glycemic control. A study conducted by Ahmed et al. (2016), found that satisfied patients had significantly lower HbA1c than their dissatisfied counterparts. Elements contributing to satisfaction include respectful communication, short wait times, and continuity of care.

Support from family, peers, and community health workers enhances motivation and provides practical help with medication, meal preparation, and transportation to clinics. In a meta-analysis of randomized controlled trials, Cheng et al. (2016) reported that participatory self-management interventions may exert beneficial effect in people with poorly controlled type 2 diabetes in decreasing HbA1c (mean difference: -0.43%, 95% CI: -0.67% to -0.18%),

enhancing diabetes knowledge (standardized mean difference [SMD]: 0.30, 95% CI: 0.03 to 0.58), improving self-efficacy (SMD: 0.29, 95% CI: 0.14 to 0.44), and decreasing diabetes-related distress (SMD: -0.21, 95% CI: -0.39 to -0.04). Self-management interventions supported with theory and structured curriculum showed desirable results in glycemic control.

Providers who communicate in a patient-centered, empathetic, and culturally sensitive manner foster trust and increase patients' understanding of care instructions. A study by Kerr et al. (2024) showed that digitally supported communication intervention led to greater reduction in HbA1c (–0.31%, 95% CI –0.45% to –0.16%; P<.001). Meta-regression estimated reductions of –0.45% (95% CI –0.81% to –0.09%; P=.02), –0.29% (95% CI –0.48% to –0.11%; P=.003), and –0.28% (95% CI –0.65% to 0.09%; P=.20) associated with high-, medium-, and low-intensity interventions, respectively. Poor communication, on the other hand, has been associated with nonadherence and poor glycemic control.

Among all determinants, DSMBs—such as medication adherence, diet, physical activity, glucose monitoring, and problem-solving—have the most direct effect on HbA1c. Systematic reviews (e.g., Magastume et al., 2022) reveal that effective DSM interventions reduced the incidence risk ratio of type 2 diabetes by 25% (0·75 [95% CI 0·61 to 0·91]), HbA1c level by 0·15% [−0·25 to −0·05], fasting plasma glucose by 3·44 mg/dL [−4·72 to −2·17], and 2-hr glucose tolerance by 4·18 mg/dL [−7·35 to −1·02]. Adherence to medication alone contributes up to 0.6% in HbA1c improvement, while combined interventions offer even greater impact.

Each of these determinants—diabetes knowledge, involvement in decision-making, self-efficacy, satisfaction with care, social support, provider communication, and self-

management behaviors—has a quantifiable and often interdependent effect on HbA1c outcomes (Gao et al., 2013; Adu et al., 2024). Interventions that address these factors holistically are more likely to achieve sustained glycemic control in T2DM patients. The evidence affirms the rationale for multi-component programmes like the IODEP, particularly in resource-limited settings, where structured education, communication improvement, and psychosocial support can significantly reduce HbA1c and improve diabetes outcomes.

2.12 Implications for Theory and Practice

The evidence reviewed in this chapter has important implications for both theory and practice. From a theoretical perspective, the research provides strong support for Social Cognitive Theory as a framework for understanding diabetes management. The evidence demonstrates the importance of all three SCT constructs and highlights the reciprocal relationships between them.

From a practice perspective, the evidence indicates that effective diabetes interventions should address personal, environmental, and behavioral factors simultaneously. Interventions that focus on only one component of the SCT framework may be less effective than comprehensive approaches that address all three components. The research also highlights the importance of tailoring interventions to specific populations and contexts. The finding that certain groups (such as younger persons, rural persons, and those with financial difficulties) may benefit less from standard interventions suggests that targeted approaches may be needed to address health disparities in diabetes care.

Thus, this literature review has provided a comprehensive examination of the evidence on diabetes management from the perspective of Social Cognitive Theory. The review demonstrates the importance of personal factors (patient involvement, knowledge, self-

efficacy, and satisfaction), environmental factors (provider support and communication), and behavioral factors (self-management behaviors) in determining diabetes outcomes.

The evidence strongly supports the use of SCT as a theoretical framework for understanding and improving diabetes care. The research shows complex relationships between the three SCT constructs and highlights the need for comprehensive interventions that address all components of the framework. The review also identifies important gaps in the literature and suggests directions for future research.

The findings of this review provide a strong foundation for the present study and highlight the importance of examining the relationships between SCT constructs in diabetes management. The evidence suggests that interventions based on SCT principles have the potential to improve diabetes outcomes, but more research is needed to optimize the design and delivery of such interventions.

2.12.1 Relationships Between Constructs

The review reveals important relationships between the three SCT constructs. Personal factors such as self-efficacy and knowledge appear to mediate the relationship between environmental factors (such as provider support) and behavioral factors (such as self-management behaviors). For example, the research by Zaini et al. (2025) found that self-efficacy enhanced the influence of social support on diabetes self-care management. Similarly, the systematic review by Almubaid et al. (2024) found that provider support promoted patient self-efficacy, which in turn increased patients' ability to manage their diabetes effectively.

Environmental factors also appear to directly influence behavioral factors. The research on provider communication and social support suggests that supportive healthcare environments can enhance patient engagement in self-management behaviors (Jones, 2024; Sharkiya, 2023). However, the relationship between environmental factors and outcomes may be mediated by personal factors such as self-efficacy and satisfaction with care.

Behavioral factors, particularly self-management behaviors, appear to be the most proximal determinants of health outcomes. The research by Gu et al. (2025) provides strong evidence that all self-management activities have positive impacts on glycemic control, with dietary control showing the greatest impact. This finding suggests that while personal and environmental factors are important, their ultimate impact on outcomes occurs through their influence on behavior.

2.13 Methodological Gaps in Reviewed Literature

The literature reviewed in this chapter revealed several methodological gaps that this study sought to address:

i. Under-Explored Contexts
    a. Existing research on T2DM management predominantly focuses on developed countries with limited studies conducted on sub-Saharan Africa and Ghana to be specific, where socioeconomic disparities are more pronounced.
    b. Cultural influences, such as preference for traditional medicine and dietary practices unique to the African context, are underexplored, despite their impact on diabetes management.

c. How IODEP study addressed it: By focusing on the Tamale Metropolitan Area and incorporating culturally relevant educational content, this study fills a contextual gap in understanding T2DM management in underserved regions.

ii. Insufficient Theoretical Integration

a. Few studies apply Social Cognitive Theory (SCT) to explore the interaction between personal, environmental, and behavioral factors affecting diabetes management in developed countries, let alone Ghana (Osei et al., 2019).

b. Research linking SCT constructs—such as self-efficacy, social support, and provider-patient communication—to clinical outcomes like HbA1c levels is lacking. At best, those that attempted mostly tries to see the effects of educational interventions on some construct(s) of SCT, not the three together.

c. How IODEP study addresses this, the study used SCT as the conceptual framework, examining how changes in psychosocial factors influence glycemic control, thus providing a theoretically grounded understanding of diabetes management in Ghana.

iii. Methodological Gaps

a. Most reviewed studies use cross-sectional designs, which cannot establish causal relationships between interventions and outcomes (Chrvala et al., 2016).

b. Quasi-experimental designs, particularly those with pretest-posttest and comparison groups, are underutilized, limiting the understanding of intervention effectiveness.

c. This study (IODEP) addressed this by employing a quasi-experimental design with a parallel non-equivalent comparison group and uses validated instruments to ensure data accuracy and relevance.

iv. Unexplored Relationships

a. Relationships between psychosocial factors (e.g., knowledge, self-efficacy, social support) and glycemic outcomes are poorly understood in many studies, especially Ghanaian studies (Mensah et al., 2021)

b. The impact of behavioral factors, such as self-monitoring of blood glucose, dietary adherence, and physical activity, on long-term glycemic control remains understudied.

c. How this study addresses it: The IODEP examines the direct and indirect effects of SCT factors on HbA1c levels, providing novel insights into the mechanisms through which behavioral changes influence clinical outcomes.

v. Population-Specific Needs

a. Marginalized populations, including older adults, women, and rural residents are mostly underrepresented in diabetes management research (Oppong et al., 2022).

b. Few studies provide culturally sensitive interventions tailored to the unique needs of these groups.

c. The IODEP addresses this, by targeting older patients from low-socioeconomic backgrounds in northern Ghana, this study provides evidence on intervention effectiveness in underrepresented populations.

Table 2.1: Summary of How the IODEP Study Addresses the Methodological Gaps

Identified Gap	Findings from Reviewed Literature	How This Study Addresses It
Under-Explored Contexts	Focus on developed nations; lack of cultural consideration.	Focuses on Tamale, Africa; integrates contextual beliefs & practices.
Insufficient Theoretical Integration	Limited use of SCT; unclear psychosocial-clinical links.	Applies SCT to examine psychosocial factors' impact on HbA1c levels.
Methodological Gaps	Overreliance on cross-sectional studies; unvalidated tools.	Uses quasi-experimental design; employs validated, culturally adapted tools.
Unexplored Relationships	Limited understanding of psychosocial-behavioral-outcome linkages.	Examines SCT factors' influence on clinical outcomes over time.
Population-Specific Needs	Underrepresentation of older adults and marginalized communities or groups.	Targets low-socioeconomic, older patients in northern Ghana.

2.14 Chapter Summary

The review establishes that effective T2DM management requires a holistic approach addressing clinical, educational, economic, and psychosocial dimensions. An examination

of the multifactorial determinants of glycemic control, moving beyond purely clinical factors to include behavioral, psychosocial, and system-level influences. The chapter adopts a social cognitive theory framework to understand how these determinants interact to influence patient outcomes. The evidence supports person-centered care models that emphasize patient activation, structured education, and comprehensive support systems. For low- and middle-income countries like Ghana, the review highlight the need for culturally appropriate, economically feasible interventions that address both individual and systemic barriers to optimal diabetes care. The chapter provides a robust foundation for understanding T2DM complexity and informs evidence-based approaches to improving diabetes care and outcomes globally.

CHAPTER 3

MATERIALS AND METHODS

3.1 Study Design

This study employed a parallel non-equivalent comparison group pretest-posttest quasi-experimental design (NEGD) to assess the effectiveness of an intervention compared to usual care for individuals with T2DM (Denny et al., 2023). Non-equivalent parallel comparison group pretest-posttest quasi-experimental design compares non-randomly allocated groups. This design exposes groups to varying levels of the independent variable (e.g., an intervention) and measures changes before and after the intervention. The terms "parallel" and "non-equivalent" suggest that the groups are treated independently and not randomly assigned.

Justification for the use of this design stemmed from the fact that random assignment was going to be difficult or impracticable due to resources, time, and accessibility to participants. Again, the fact that the design could allow me to collect longitudinal data by studying group changes over time to reveal trends and patterns related to the study outcomes was another reason for the choice. In effect, the choice of this design was informed by the fact that it allows researchers confronting ethical, logistical, or external validity constraints to derive relevant findings related to the effects of interventions in real-world contexts.

The trial commenced with a baseline assessment which was subsequently followed by a 6-month intervention protocol. The study included patients with T2DM who visited outpatient diabetes clinics at two selected public health facilities (Tamale Teaching Hospital and Tamale Regional Hospital) in the Tamale Metropolitan Area (TAMA). TAMA houses

several hospitals, including Tamale Teaching Hospital (TTH), Tamale Regional Hospital (TRH), Tamale West Hospital, Seventh-Day Adventist Hospital, Kamina Barracks Hospital, among others. The two health facilities (TTH and TRH) were purposively selected primarily because of the high volumes of outpatient diabetes clinic attendees each recorded. After the selection, the two health facilities and not the study participants were randomly allocated to either the intervention or comparison groups using a simple lottery method. Names of the two health facilities were written on pieces of paper and folded. A ground rule was then set to the effect that the facility to be picked first was to be assigned the intervention and vice versa. Haven established this ground rule, a third person unrelated to the study and participants was invited to do the picking, leading to the allocation of TTH to the intervention group and TRH to the comparison group. Data on HbA1c levels and variables related to personal, environmental, and behaviour were measured in both groups at baseline. The intervention group (TTH) received a diabetes education and support programme for six months (the intervention), while the comparison group received standard medical treatment from the TRH.

The study assessed the impact of the intervention on the primary outcome (HbA1c) and secondary outcomes, both before and during the intervention. The baseline data was assessed for similarity using appropriate summary statistics. Intention-to-treat analysis was used to address missing data. Parametric tests were conducted under the assumption of a normal distribution for the primary outcome variable. The study assessed the impact of the intervention on the outcome variables through the application of repeated measure ANOVA and multivariate regression analysis. Cohen's convention was utilized to estimate and classify effect sizes in the two groups. Figure 3.1 presents the study layout or schemic design of the study.

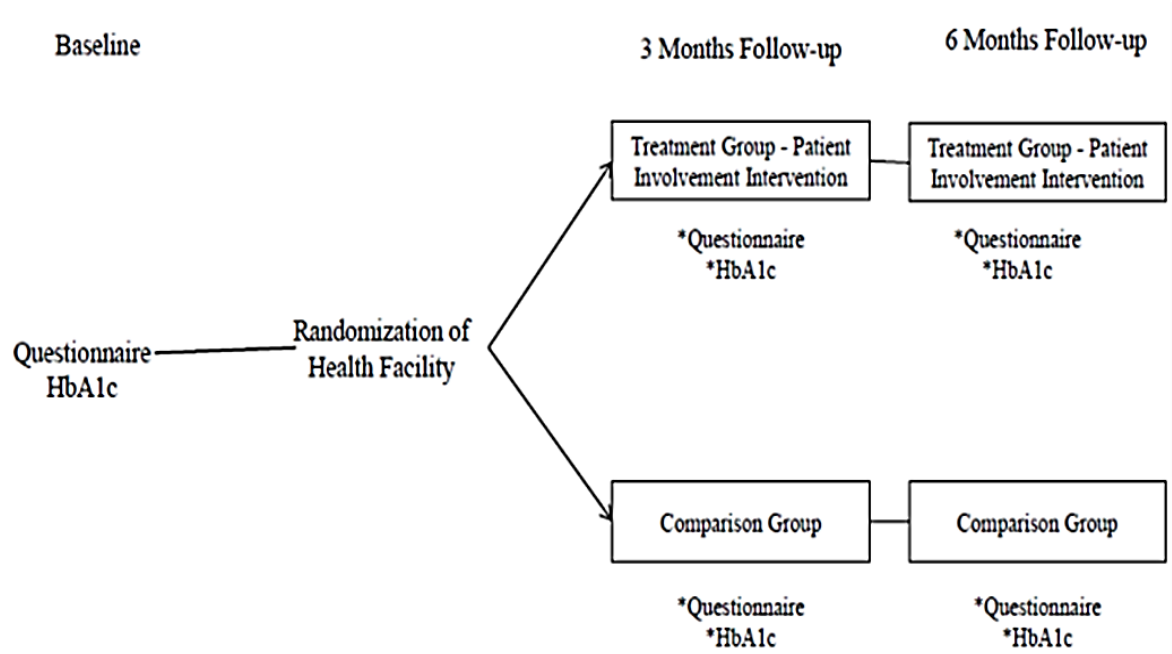

Figure 3.1: Study Design and Outcome Determination

3.2 Study Location

The study was conducted in the Tamale Metropolitan Area (TAMA), Northern Region, Ghana. TAMA is the only metropolis in Northern Ghana, covering 922 km² with a population of approximately 450,000, comprising 116 communities (52% rural, 13% peri-urban, 35% urban) (Fuseini et al., 2017; Ghana Statistical Service, 2014).

3.2.1 Healthcare Facilities

Tamale Teaching Hospital: A tertiary referral hospital established in 1974, affiliated with the University for Development Studies. The hospital has 341 beds and operates specialized diabetes clinics on Tuesday and Fridays, staffed by one medical doctor and six nurses. In 2019, TTH had 934 registered diabetes patients, with 915 diagnosed with Type 2 diabetes.

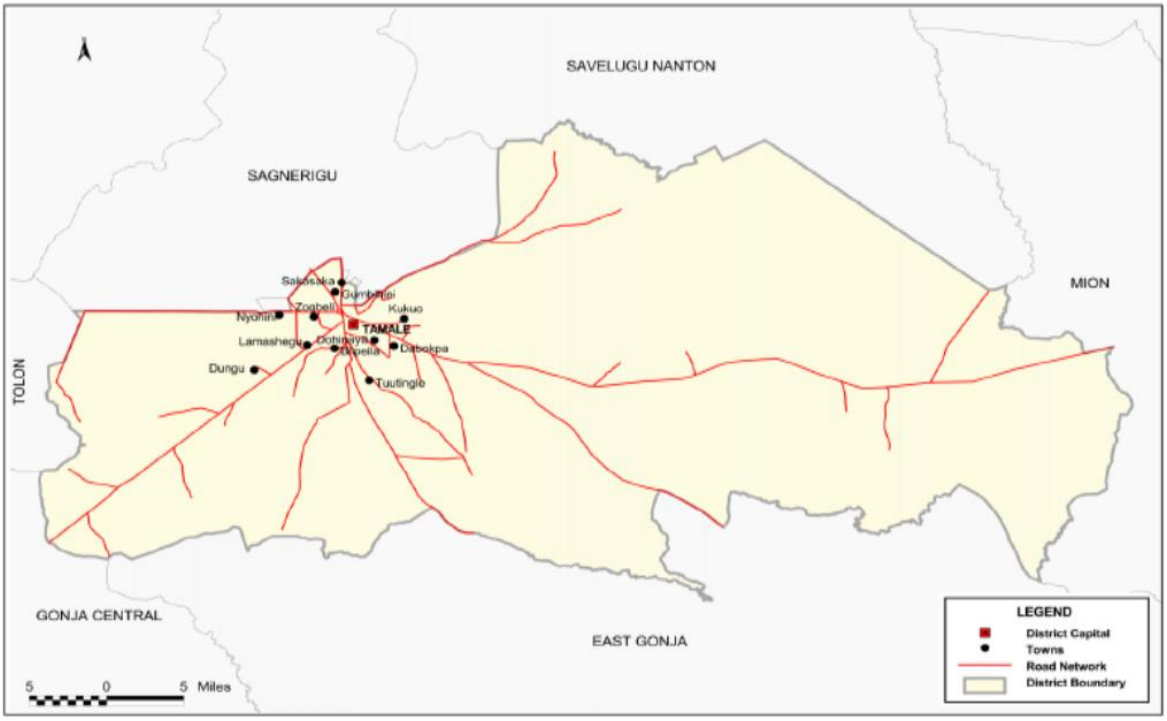

Figure 3.2: Map of the Tamale Metropolis

Source: Ghana Statistical Services (2014)

The Tamale Regional Hospital (TRH): A public healthcare facility originally established in 1928, reopened in 2005, with 255 beds. The hospital operates a weekly diabetes clinic on Thursdays, staffed by one physician, two nutritionists, and two nurses. 1n 2018. TRH had 537 registered diabetes patients. Diabetes ranked as the second highest cause of mortality at TRH in 2019-2020.Both TTH and TRH serve as primary healthcare providers for diabetes management in northern Ghana, though they face challenges including limited resources, staff shortages, and extended waiting time.

3.3 Study Variables

The study incorporated variables that were measured through a questionnaire guided by constructs of social cognitive theory. The predictor variable's (IODEP) effectiveness was

assessed based on its impact on the independent variables. The dependent variables consisted of two categories: the primary (HbA1c), and secondary outcomes (personal, environmental, and behavioural factors). The anticipated impact of the predictor variable (IODEP) was expected to cause changes in the dependent variables.

3.4 Primary and Secondary Outcome Variables

3.4.1 Primary Outcome Variable

i. HbA1c (HbA1c) level. This outcome variable is aligned with specific objectives 1 and 5 which explicitly focused on assessing to understand the effect of the IODEP on HbA1c levels in patients with T2DM.

3.4.2 Secondary Outcome Variables

i. Personal factors comprised of patient involvement in the treatment decision-making process; knowledge of diabetes; decision-making self-efficacy; and satisfaction with care. This aligns with objective 2, which aims to determine the effect of IODEP on personal factors.
ii. Environmental factors, comprised of the provider's communication style, and social support received from providers, align with objective 3, which sought to determine the effect of IODEP on environmental factors.
iii. Behavioural factor, comprised of diabetes self-management behaviours. It aligns with objective 4 which sought to assess and understand the effect of IODEP on self-management behaviours.

3.4.3 Predictor Variable

The predictor variable was considered to be stable, and unaffected by the variables under investigation. The intervention, which is typically considered the presumed cause, was

consistently and systematically manipulated by the investigator through the intervention (IODEP) implemented. The study utilized the Intensive Outpatient Diabetes Education Programme (IODEP) as the independent variable. The primary and secondary outcomes were measures to assess the impact of IODEP on these variables, especially among participants in the intervention group.

3.4.4 Covariates

Participants' age, gender, education, marital status, and length of disease are covariates.

3.5 Population under Study

The study recruited participants from two public health facilities in the Tamale Metropolitan Area (TAMA) through convenience sampling. The study's inclusion criteria mandated that participants be 18 years of age or older, have a confirmed diagnosis of T2DM, and receive routine medical care at either the intervention or comparison health facility as outpatients. The study included both newly diagnosed and previously diagnosed patients with T2DM. Participants who were either critically ill or unable to provide informed consent were excluded. Participants were eligible to participate if they met the specified inclusion criteria.

3.5.1 Inclusion Criteria

Participants in the study were included if they met the specified criteria set for the study and these included: a) a confirmed diagnosis of T2DM with other concomitant diseases based on the World Health Organization criteria (World Health Organization, 2003), at least 3 months before the start of the investigation; b) age 18 years or older; c) a recent blood test result showing HbA1c >7%; d) self-reported use of at least one medication; e) identification as Ghanaian, recent visit to a diabetes clinic within the past six months, and no history of

frequent default healthcare appointments, unstable psychiatric problems or a terminal prognosis.

3.5.2 Exclusion Criteria

Participants were excluded based on the following criteria: i. not being continuing patients (defined as a patient who failed to make three prior visits to the clinic within a year – defaulting patients), ii. Feeble over 70 years old with no reliable family support, iii. experiencing serious complications such as severe stroke or severe renal problems that may hinder their ability to be engaged fully in the study process, iv. having a history of significant psychiatric disorders, and v. having an HbA1c level consistently to the target—an indication that the person's diabetes is well managed and his/her blood sugar levels are consistently within their target range.

3.6 Sample Size Calculations for Quasi-Experimental Design

The statistical methodology for sample size calculation in quasi-experimental studies builds upon the foundation established for randomized controlled trials while incorporating adjustments for the unique characteristics of non-randomized designs (Campbell & Stanley, 1963). The fundamental challenge lies in accounting for potential bias, increased variability, and reduced statistical efficiency while maintaining practical feasibility and scientific rigor (Reichardt, 2009).

The basic formula for sample size calculation in quasi-experimental studies modifies the standard two-group comparison formula to include a design effect factor, $n = DE \times 2 \times (Z_{\alpha/2} + Z_{\beta})^2 \times \sigma^2 / \delta^2$ where: - n = sample size per group, - DE = design effect (typically 1.1 to 1.4 for quasi experimental studies), - $Z_{\alpha/2}$ = critical value for Type I error ($\alpha = 0.05$, $Z_{\alpha/2} = 1.96$), - Z_{β} = critical value for Type II error ($\beta = 0.20$ for 80% power, $Z_{\beta} = 0.84$),

- σ = standard deviation of the outcome measure, and - δ = effect size (difference between groups).

3.6.1 Primary Analysis: HbA1c Outcome with Design Effect Adjustment

The primary outcome for the IODEP quasi-experimental study is the change in HbA1c levels between intervention and comparison groups, accounting for baseline differences and potential confounding through statistical adjustment. Based on the literature review of quasi-experimental diabetes interventions, the following parameters were established for sample size calculation.

Expected Standard Deviation (σ): 1.6% This value represents the median standard deviation observed in quasi-experimental diabetes intervention studies, accounting for the increased variability typical of non-randomized designs. The value is higher than the 1.3% used in randomized trial calculations, reflecting the greater heterogeneity in participant characteristics and implementation contexts common in quasi-experimental studies (Blonde et al., 2018).

Expected Effect Size (δ) is 0.7% This effect size is based on the median HbA1c reduction observed in facility-based quasi-experimental diabetes interventions. The larger effect size compared to randomized trials (0.65%) reflects both the potential for greater real-world effectiveness and the need for larger effects to achieve statistical significance in the presence of potential confounding (Garber et al., 2019). The **Design Effect (DE)** is 1.25. This design effect accounts for the facility-based allocation and potential baseline differences between intervention and comparison sites, based on empirical estimates from similar quasi-experimental studies (Kahn et al., 2006). The **resulting Cohen's d** = 0.7/1.6 = 0.44 (small

to medium effect size). **Sample Size Calculation**: Using the quasi-experimental design formula with 85% power:

$$n = 1.25 \times 2 \times (1.96 + 1.04)^2 \times (1.6)^2 / (0.7)^2$$

$$n = 1.25 \times 2 \times (3.00)^2 \times 2.56 / 0.49$$

$$n = 1.25 \times 2 \times 9.00 \times 2.56 / 0.49$$

$$n = 117.6 \approx 118 \text{ per group}$$

Adjustment for Dropout: Accounting for an anticipated 15% dropout rate (higher than randomized trials due to potential differential attrition):

n_adjusted = 118 / (1 - 0.15) = 138.8 ≈ 139 per group

Hence, the total sample size = 278 participants

3.6.2 Initial Assessment

A total of 485 individuals were assessed for eligibility, including 285 from the treatment group hospital (TTH) and 200 from the treatment comparison hospital (TCH). During the first exclusion phase, 209 participants were removed from the study. At TTH, 140 participants were excluded: 46 were found to have type 1 diabetes, 94 withdrew voluntarily, 74 were excluded due to geographical distance, and 20 were removed for unspecified reasons. At TCH, 69 participants were excluded: 40 had type 1 diabetes, 29 withdrew from the study, 18 were excluded because of geographical distance, and 11 for reasons that were not specified.

3.6.3 Medical Screening Phase

Following the initial exclusions, 276 participants proceeded to medical screening, comprising 145 from the Treatment Group Hospital (TTH) and 131 from the Treatment

Comparison Hospital (TCH). During this phase, 31 additional participants were excluded due to the development of complications—20 from TTH and 11 from TCH.

3.6.4 Baseline Measurements

After exclusions during medical screening, 245 participants remained and completed baseline measurements for all primary and secondary outcomes. This group consisted of 125 participants from the Treatment Group Hospital (TTH) and 120 from the Treatment Comparison Hospital (TCH). Participants were then assigned according to facility in a non-equivalent group design: the 125 individuals from TTH received the intervention, while the 120 from TCH continued with standard care.

3.6.5 Final Study Groups

In the final study groups, 125 participants from the Treatment Group Hospital (TTH) formed the intervention arm. They received the Intensive Outpatient Diabetes Education Programme (IODEP) in addition to the usual care provided during their regular visits. The comparison group consisted of 120 participants from the Treatment Comparison Hospital (TCH), who continued to receive standard care as typically provided during routine appointments.

3.6.6 Primary Analysis

All participants recruited from both facilities were included in the primary analysis. This comprised 125 individuals in the intervention group and 120 in the control group, giving a total of 245 participants analyzed.

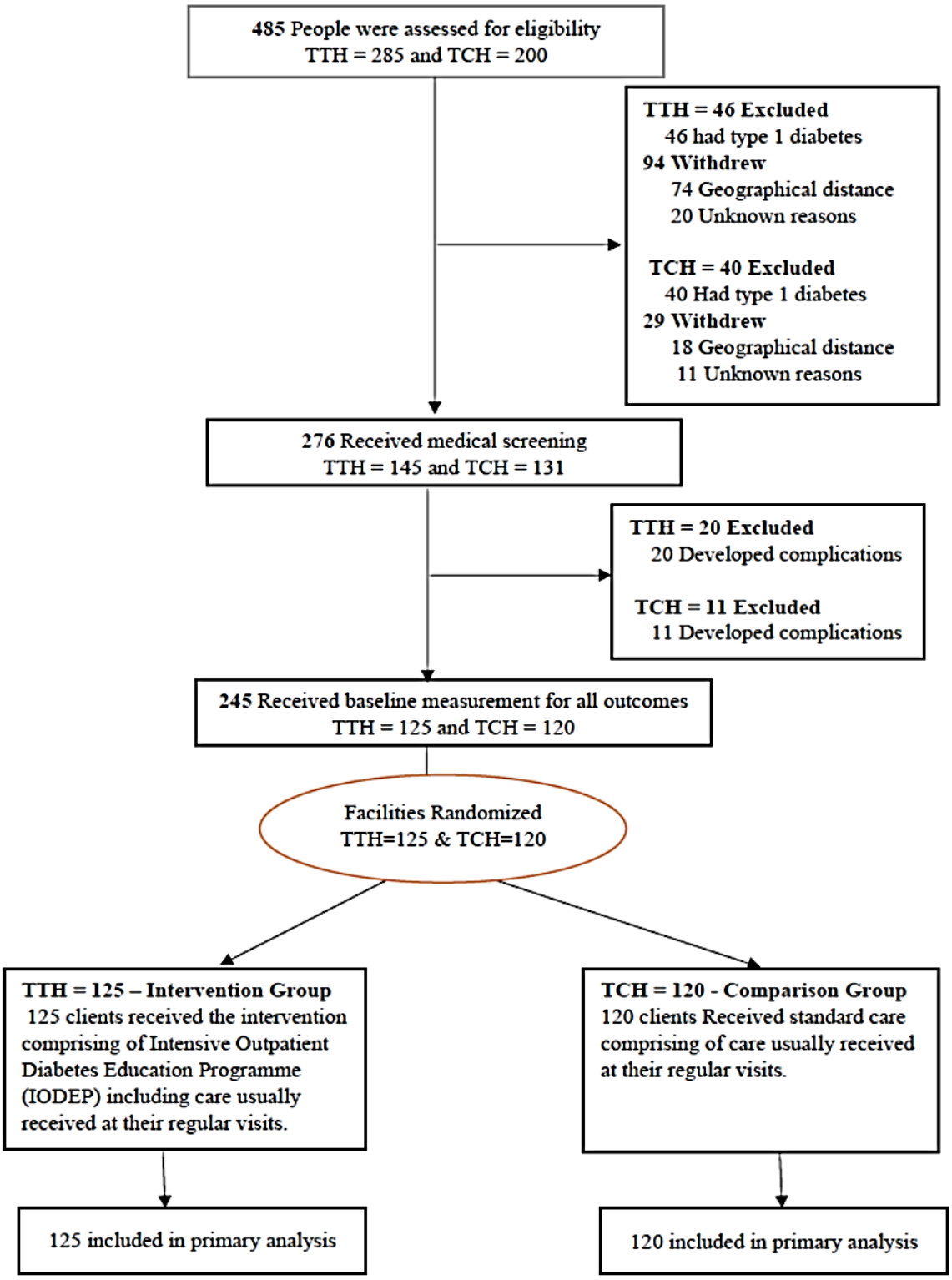

Figure 3.3: Flowchart of Participants recruitment into the Study

3.6.7 Sampling Procedure

This study purposively selected two hospitals among many in the Tamale Metropolitan Area (TAMA) that are known for operating diabetes clinics. These hospitals were then randomly assigned to either the comparison or the intervention groups. TRH served as the comparison group, while TTH served as the intervention group. These two facilities conducted weekly diabetes clinics on specific days, which coincided with the days the study participants were sampled. All individuals aged 18 or older with confirmed T2DM who attended follow-up office visits at either of the two study facilities were considered potentially eligible for participation in the study. These individuals were enrolled in the study in sequential order during their follow-up care visits. Interested participants underwent two screening processes and were asked to complete a baseline assessment questionnaire to determine if there were any initial differences between the intervention and comparison groups.

To minimize contamination of the comparison group, the study employed the following strategies: random allocation of the two study facilities (TTH and TRH) to the intervention and comparison groups, respectively, and ensuring a distance of 1-2 kilometers between them. This approach, supported by previous research (Magill et al., 2019; Stamp et al., 2021), reduced the likelihood of contamination. Furthermore, to maintain the integrity of the comparison group, the principal investigator (PI) strictly adhered to the principle of providing only standard or routine care to participants. No partial interventions or compensating activities were carried out with the comparison group (Cook & Campbell, 1979; Borg, 1984). Additionally, the PI devised a technique to evaluate the interaction and exchange of information between the two groups. This was accomplished by asking a set of contamination-related questions during each phase of data collection. The responses to the

questions were used to determine if the comparison group was aware of specific intervention components or had adopted suggested intervention behaviours.

Doyle and Hickey (2013) found that implementing strategies such as social or physical separation, complex interventions targeting behaviour change, and cluster randomization can effectively reduce the likelihood of contamination. By employing these strategies, the intervention's effectiveness on the intervention group was significantly improved while minimizing any influence on the comparison group.

3.6.8 Data Collection Methods and Tools

A comprehensive structured questionnaire, divided into sections, was employed to collect quantitative data on various factors of interest. Both the intervention and comparison groups were administered a questionnaire to assess the relevant variables at baseline, three months later, and six months later. The data sources consisted of patients with T2DM who met the inclusion criteria, were enrolled in the study, provided consent, and were receiving care at the outpatient diabetic clinics of TTH or TRH.

Schofield and Forrester-Knauss (2013) recommended the use of structured questionnaires in health research studies for quantitative data collection due to their ability to standardize data collection and facilitate evaluation using statistical tools. The study utilized a questionnaire to collect data on various aspects related to the patient's sociodemographic characteristics, involvement in decision-making, social support, diabetes knowledge, self-efficacy in decision-making, satisfaction with care, assessment of provider communication style, diabetes self-management routines, and HbA1c. Previous studies have used similar questionnaires to assess patients' experiences and outcomes in diabetes management, which

informed the design and content of our questionnaire (Toobert et al., 2003; Chomutare et al., 2011; Cotter et al., 2014).

Data was collected over twelve months, from March 2021 to February 2022. The study employed repeated measures analysis of covariance to assess changes between the intervention and comparison groups across three time periods, as well as any potential interaction effects. The study required a minimum sample size of 142 individuals. However, to enhance statistical power, an additional 103 participants were included in the sample to enhance the study statistical power, internal and external validity, and reliability.

Table 3.1: Study Variables

Variable	**Measurement Tool/Instrument**
Primary Outcome	
Glycosylated Haemoglobin Level	Quo-Lab HbA1c Analyzer (EKF Diagnostics for Life)
Secondary Outcomes	
Personal Factors	
Patient Involvement	The 'Involvement Indicators Subscale' of a questionnaire developed by Tambuyzer & Audenhove (2013)
Disease-specific Knowledge	The Spoken Knowledge in Low Literacy in Diabetes (SKILLD) Knowledge Assessment Scale (Rothman et al., 2005)
Decision-Making Self-efficacy	Self-efficacy scales (Schwarzer & Renner, 2000)
Satisfaction with decision	Satisfaction with decision subscale of CDIS-P (Slade et al., 2014)
Environmental Factors	
Social support received	Subscale (Section V) of Diabetes Care Profile (DCF2.0) (Michigan Diabetes Research and Training Centre, 1998)
Provider communication style	Communication Assessment Tool (Makoul, 2004)
Behavioural Factor	
Self-management practices	Diabetes self-management questionnaire (DSMQ), (Schmitt et al., 2013)
Predictor Variable	
The Intervention (Intensive Outpatient Diabetes Education Programme)	Survey

Baseline measurements included demographic variables such as age, marital status, gender, ethnicity, religion, education level, occupation, monthly income, health insurance status, place of residence, as well as variables related to health, such as severity and duration of

disease, and type and quantity of drugs used. To determine the potential influence of these variables on the study's results, they were assessed.

The primary outcome measure was glycosylated hemoglobin (HbA1c), assessed using the Quo-Lab HbA1c Analyzer (EKF Diagnostics). HbA1c reflects average blood glucose over the previous two to three months and is the gold standard for evaluating long-term glycemic control. As a laboratory-based tool, the analyzer's reliability derives from its precision and reproducibility rather than psychometric properties, and its validity is supported by strong associations with diabetes complications.

Personal factors were assessed across four domains. Patient involvement in decision-making was measured using the Involvement Indicators Subscale (Tambuyzer & Audenhove, 2013), a seven-item tool with good internal consistency ($\alpha = 0.846$). Disease-specific knowledge was evaluated with the SKILLD scale (Rothman et al., 2005), a 10-item oral test designed for low-literacy populations, which demonstrated acceptable reliability (KR = 0.72) and meaningful correlations with HbA1c. Decision-making self-efficacy was measured with the 10-item General Self-Efficacy Scale (Schwarzer & Jerusalem, 1995), validated internationally with strong psychometric properties ($\alpha = 0.76–0.90$). Satisfaction with decision-making was captured using the six-item satisfaction subscale of the Clinical Decision-making Involvement and Satisfaction Scale – Patient version (CDIS-P), which showed excellent reliability ($\alpha = 0.90$) and predictive validity for treatment implementation.

Environmental factors included social support, measured with Section V of the Diabetes Care Profile (DCF2.0; $\alpha = 0.919$), which assesses support from family, friends, and providers, and provider communication, assessed with the 15-item Communication

Assessment Tool (CAT), a validated measure of physician–patient communication effectiveness.

Behavioral factors were assessed using the Diabetes Self-Management Questionnaire (DSMQ; Schmitt et al., 2013). This 16-item tool measures glucose management, dietary control, physical activity, and healthcare use. It demonstrated good internal consistency ($\alpha = 0.84$ overall) and strong correlations with HbA1c ($r = -0.40$ for the sum scale).

Finally, the predictor variable, i.e., exposure to the Intensive Outpatient Diabetes Education Programme (IODEP), was assessed using a custom survey instrument capturing participation and program-related experiences.

Table 3.2: Instruments Overview and Basic Characteristics

Instrument	Domain	Items	Scale Type	Administration Time	Target Population
Quo-Lab HbA1c Analyzer	Primary Outcome	N/A	Laboratory Analysis	Varies	Diabetes Patients
Involvement Indicators Subscale	Personal Factor	7	5-point Likert	Not specified	Healthcare Patients
SKILLD	Personal Factor	10	Open-ended Oral	~4 minutes	Low Literacy Diabetes Patients
General Self-Efficacy Scale	Personal Factor	10	4-point Likert	4 minutes	General Adult Population
CDIS-P Satisfaction Subscale	Personal Factor	6	5-point Likert	Not specified	Healthcare Patients
Diabetes Care Profile Section V	Environmental Factor	Part of 234	Mixed	30–40 minutes	Diabetes Patients
Communication Assessment Tool	Environmental Factor	15	Patient Ratings	Not specified	Healthcare Settings
DSMQ	Behavioral Factor	16	Not specified	Not specified	Type 1 & 2 Diabetes

Table 3.3: Reliability Coefficients and Validity Evidence

Instrument	Cronbach's Alpha	Key Validity Evidence
Involvement Indicators	0.846	Factor analysis confirmed structure
SKILLD	0.720	Correlates with HbA1c (r = -0.16)
General Self-Efficacy Scale	0.760-0.900	Extensive cross-cultural validation
CDIS-P Satisfaction	0.900	Predicts decision implementation
Diabetes Care Profile (Section V)	0.919	Predicts self-management behaviours
Communication Assessment Tool	0.923	Predicts satisfaction with care, among others
DSMQ Total	0.840	Strong HbA1c correlations (r = -0.40)

3.7 Activities before Data Collection

3.7.1 Gaining Health Facilities Access

The Principal Investigator (PI) submitted a formal letter to the selected facilities administrators, seeking permission to conduct primary research at the two facilities. Letters were also sent to those facilities from the Regional Health Directorate, Northern Region. Also, copies of the approved ethical clearance letter from the Ghana Health Service Ethical Review Committee were served them. The letters primarily requested for support from the two facilities to assist the student carry his research without any hitch. Furthermore, formal discussion sessions with gatekeepers at both facilities were held to provide information about the study before its commencement.

3.7.2 Training Research Assistants

Four research assistants were hired to assist with the conduct of the study. The PI arranged a three-day training session for the research assistants after they were hired and before the

start of the researcher proper. All members of the team were undergraduates and possessed various expertise coming from several years of practice (Nutritionist, Nurse, and Health Educationist). They were recruited specifically to assist in the conduct of the study (facilitate intervention group participants structured educational training and subsequent support sessions with patients in their homes prior for their scheduled healthcare visits). The training provided comprehensive instruction on the necessary concepts and techniques for the intervention, educational sessions facilitations, and questionnaire administration, with a focus on following the study protocol requirements.

3.7.3 Pilot Study

A pilot study is a smaller-scale version of a larger version that is conducted to evaluate research tools and processes and to make improvements to various aspects of the research process, where necessary (In, 2017). These tools were utilized to assess the suitability and relevance of data collection techniques, as well as to evaluate the investigator's level of interest, capability, and dedication to the project (Hassan et al., 2006; In, 2017). Pilot studies serve as a platform for conducting a dress rehearsal to identify opportunities for enhancing the research process (Hassan et al., 2006; In, 2017).

A pilot study was conducted from January 2021 to February 2021 to assess the feasibility and practicality of the research process, including intervention implementation, data collection procedures, sampling methods, and data analysis techniques. Thus, the purpose of the pilot study was to evaluate the entire research process before proceeding with the full-scale implementation.

The study sampled 40 T2DM patients from West Hospital in Tamale who exhibited similar characteristics to the study subjects. Based on the pre-test results, decisions were made

regarding the modification and removal of some items in the questionnaire that exhibited poor loading on the scale. Some sections of the survey questionnaire were modified. For example, marital status was recategorized as either married or single (encompassing individuals such as spinsters, widows, and those who were divorced or separated). The religious denomination was recategorized to include Islam, Christianity, and other religions. Traditional religion was removed. For ethnicity, the initial five categories were regrouped into three categories: Dagomba, Akan, and others. Occupation was replaced with employment status, and a follow-up question was added regarding the sector employed in if the respondent indicated they were currently employed. The employment status question was divided into two categories: employed and unemployed. Item 3 in the Likert scale questionnaire measuring 'Satisfaction with Decision Subscale of Clinical Decision-Making Participation and Satisfaction', was excluded due to its inadequate performance on the internal consistency test, as measured by Cronbach's alpha. The internal consistency (Cronbach's alpha) of the subscale increased from 0.668 to 0.821 after its removal. The initial scale measuring social support included both formal support from health providers and informal support from family and friends. Responses from the pilot study indicated that informal support was not a problem as it provided the needed supportive environment for self-management activities. The individuals were primarily concerned with enhancing formal support systems to cater to their specific needs. Consequently, the questionnaire omitted items from the social support scale intended to assess informal support.

Furthermore, a significant piece of information was obtained that resulted in the decision to relocate implementation of the educational intervention away from the hospital setting to the residences of the participants. Informal discussion sessions which offered respondents the environment to freely express themselves including the rolling out of free HbA1c test for

participants, among others, played a significant role in achieving a zero percent loss to follow-up rate in this study.

3.8 Roles of Research Assistants and Principal Investigator

3.8.1 The Role of the Principal Investigator

The Principal Investigator maintains comprehensive oversight of the quasi-experimental study design while ensuring that both intervention delivery at TTH and comparison group management at TRH contribute effectively to the research objectives. This leadership role requires balancing the distinct requirements of intervention implementation and comparison group monitoring while maintaining scientific rigor and methodological validity across both study conditions.

Scientific direction includes development of standardized protocols that ensure comparable data collection across both sites while maintaining appropriate distinctions between intervention and comparison conditions. The PI ensures that research procedures were implemented consistently while intervention delivery remains distinct to the TTH site and standard care practices are maintained at the TRH site.

The PI's oversight includes regular monitoring of intervention fidelity at TTH to ensure that the IODEP programme is delivered as designed while simultaneously monitoring comparison group management at TRH to ensure that standard care practices are maintained without inadvertent introduction of intervention components. This dual monitoring approach ensures that both study conditions contribute valid data for comparative analysis.

Comparative analysis planning includes development of statistical approaches that account for the quasi-experimental design while addressing potential confounding factors that may

arise from facility-level differences. The PI ensures that analytical approaches are appropriate for the study design while providing valid assessment of intervention effectiveness compared to standard care. The PI also maintains responsibility for ensuring that ethical standards and study fidelity are maintained across both study conditions while participants in both groups receive appropriate care and support. This includes monitoring participant safety and satisfaction at both sites while ensuring that research procedures do not compromise clinical care quality at either facility.

3.8.2 The Role of Research Assistants

Research Assistants at both TTH and TCH participate in coordinated activities that ensure consistency in research procedures while maintaining appropriate separation between intervention and comparison conditions. These coordination activities require careful attention to sharing necessary research information while preventing contamination between study groups.

Coordinated data collection protocols include standardized procedures for assessment administration, synchronized timing of data collection activities, comparable quality assurance procedures, and coordinated reporting of research progress and issues. These protocols ensure that research data are collected consistently across both sites while maintaining the distinctions necessary for valid comparative analysis.

Communication protocols include regular coordination meetings that focus on research procedures and data collection issues while avoiding discussion of intervention-specific content that could lead to contamination. These communications ensure that research activities proceed smoothly while maintaining appropriate boundaries between study conditions.

Training coordination includes joint training sessions on research procedures and data collection protocols while maintaining separate training for intervention-specific and comparison-specific responsibilities. This approach ensures that all research personnel understand overall study objectives while maintaining appropriate role distinctions.

Quality assurance coordination includes comparative review of data quality and protocol compliance across both sites, identification of discrepancies that may indicate quality issues, and coordinated corrective action that addresses quality concerns while maintaining study group separation. These activities ensure that research quality is maintained consistently across both study conditions.

3.9 Baseline (Pre-Intervention) Survey

A baseline survey was conducted following the enrolment of eligible participants into the study. The survey aimed to evaluate the demographics of study participants and assess their involvement in their care process, disease-specific knowledge, self-efficacy, satisfaction with care, self-management behaviours, perceived support received, patient evaluation of provider communication style, and glycemic control. Glycemic control was the primary outcome measured in both the intervention and comparison groups. Participants were requested to provide their consent prior to the launch of the survey. The eligible participants of the study were provided with an information sheet specifically designed to provide details about the trial. Every participant in the study was required to provide informed consent by signing a designated written consent form after being informed about the study and making the decision to participate. The study adhered to all relevant ethical considerations, including anonymity, confidentiality, and the participant's right to withdraw from the study at any time. Participants were encouraged to provide independent responses to the questionnaire,

and all completed forms were received and securely stored. The intervention group participants were subsequently placed on the intervention programme.

3.9.1 Tamale Teaching Hospital and Tamale Regional Hospital: Key Similarities

Quasi-experimental designs can be useful in situations where randomization is difficult or not feasible, although they do carry the potential for bias. It is therefore crucial to implement rigorous strategies to mitigate potential biases to ensure the credibility and validity of study results. To ensure that transparency in research is not compromised, it is important to acknowledge and address any potential biases and limitations in the study. Some strategies were adopted including comparing similarities in the patient population, operational and treatment similarities, and geographical and cultural considerations to control for confounding variables to ensure the validity and reliability of the study findings. A thorough consideration of these aspects, among others, were seen to be the necessary prerequisite to help improve the internal validity of quasi-experimental studies.

Patient Population and treatment-related variables were compared at the start to match participants in the intervention and comparison groups based on relevant demographic characteristics such as age, gender, and duration of diabetes, among others, and there was no significant variation in patients' demographics and treatment-related factors in the two groups, indicating that the two groups were comparable at the start of the study.

Again, the two facilities/groups demonstrated similarity in terms of standardized operational procedures and treatment protocols related to T2DM management. Both had a single physician and about five nurses and other staff running their respective diabetes clinics. There were neither endocrinologists nor diabetologists nor any qualified diabetes educators in either facility. They both also employed unstructured operational procedures heavily

influenced by patients' requests. Hence, they were comparable in terms of operational and treatment factors.

The establishment of these similarities at baseline helped minimize variability in care provided in both facilities and ensured consistency and reliability. The strategy also helped to guarantee confidence in ascribing variations in results obtained to the intervention implemented. The intervention was also gradually introduced instead of wholesale implementation at once, enabling a comparison of outcomes over time. This effectively helped in controlling for confounding variables and trends.

Furthermore, similarities in geographical and cultural factors were compared and achieved through the selection of patient populations that were similar based on geographical and cultural factors including being Ghanaian, mainly residents of the region where the two facilities are located, were predominantly Dagombas and Muslims with similar norms and belief system, among others. This approach helped to minimize biases associated with these considerations.

3.10 Study Duration and Phase-Wise Timeline of the IODEP Study

The Intensive Outpatient Diabetes Education Programme (IODEP) was a six-month longitudinal study designed to assess the short- and long-term impact of a structured diabetes education intervention on older/vulnerable adults with type 2 diabetes. The timeline was deliberately chosen to ensure measurable changes in psychosocial factors, diabetes self-management behaviors, and clinical outcomes such as hemoglobin A1c (HbA1c) levels, while keeping the participant retention rate high.

3.11 Study Duration and Design Rationale

A six-month duration strikes a critical balance, it provides sufficient time for both behavioral change and physiological adaptation (particularly HbA1c, which reflects glucose control over 8–12 weeks) while remaining feasible for participants. The timeline enabled a structured, phased approach to behavior change—beginning with knowledge acquisition and skill development, followed by behavior maintenance and reinforcement. The study design featured three assessment points: baseline (pre-intervention), three months (mid-intervention), and six months (post-intervention). This tri-phasic data collection allowed researchers to track both immediate and sustained effects of the intervention.

The schedule aligns with best practices in diabetes education research and corresponds to typical clinical follow-up schedules (i.e., every 3–6 months). Additionally, the timeframe was carefully selected to avoid potential confounding seasonal changes that could influence physical activity, diet, and glucose levels.

3.12 Phase 1: Baseline to 3-Month Assessment (Initial Intervention Period)

The initial phase of the intervention spanned 90 days and focused on providing participants with core diabetes self-management knowledge and skills. A comprehensive baseline assessment was conducted to measure glycemic control (HbA1c), along with personal, environmental, and behavioral factors. Participants attended structured educational sessions led by the research team, covering diabetes pathophysiology, glucose monitoring, medication use, nutrition, physical activity, and management of hypoglycemia (see Appendix III). Support was reinforced through biweekly or monthly contacts, where participants identified concerns, set goals, practiced problem-solving, and developed question-asking skills. Additional telephone follow-ups addressed ongoing educational and

support needs. The overall aim was to reduce barriers, strengthen skills, and promote better health outcomes. The three-month point was selected because evidence indicates that behavioral changes and early improvements in glycemic control typically emerge within 8–12 weeks. A mid-study assessment was then conducted to evaluate intervention effects, participant engagement, and fidelity of implementation.

3.13 Phase 2: 3-Month to 6-Month Assessment (Behavior Maintenance Period)

Phase 2, spanning months three to six, focused on the maintenance of behaviors established during the initial intervention. Participants continued to receive support at a reduced intensity, with an emphasis on reinforcing positive behaviors, developing long-term plans, and applying problem-solving strategies. Attention was given to barriers such as waning motivation, lifestyle adjustments, and the need for sustained social support. Educational sessions and follow-ups promoted autonomy in self-care, refinement of glucose monitoring practices, and adaptation of behaviors to changing circumstances. The six-month assessment, serving as the study's primary endpoint, evaluated the cumulative impact of the intervention using the same tools applied at baseline and mid-study.

3.14 Temporal Design Considerations and Methodological Strengths

The two-phase, six-month study design offered both clinical and analytical benefits by distinguishing immediate from sustained effects and framing behavior change as a process of acquisition followed by maintenance. This structure allowed for mid-course evaluations, adaptive refinements to the educational approach, and comparison of trends across clinical, behavioral, and psychosocial outcomes. The timeline also reflected the typical learning curve in diabetes self-management, recognizing that while some participants adapt quickly, others require more time. This flexibility enhances the generalizability of the findings.

3.14.1 Primary Outcome Variable

Three assessment points—baseline, three months, and six months—structured the data collection process:

i. Baseline: Established participants' pre-intervention status across all outcome domains.
ii. Three-Month Assessment: Focused on early indicators of change and identified participants requiring additional support. It also gauged the acceptability and feasibility of the educational intervention.
iii. Six-Month Assessment: Served as the definitive measure of the intervention's effectiveness across clinical, behavioral, and psychosocial outcomes.

3.15 Justification for Six-Month Duration

The six-month period is scientifically grounded in the behavioral and biological timelines necessary for significant diabetes-related changes. Research supports the need for at least 12 weeks to initiate behavior change and 4–6 months to ensure stability. The duration aligns with standard clinical practice, maximizing real-world applicability and integration potential.

From a clinical standpoint, HbA1c measurement over this period provides a reliable metric of glycemic control. From a behavioral standpoint, the study could observe the full cycle of behavior initiation and maintenance, including drop-offs or plateau phases. It also allowed for evaluation of changes in psychosocial constructs like self-efficacy, diabetes-related distress, and quality of life.

The IODEP study's six-month, phase-wise design ensured a methodologically sound, clinically relevant, and participant-centered evaluation of diabetes education. By segmenting

the study into education-intensive and maintenance-focused phases, with comprehensive assessments at each point, the study effectively captured both short-term changes and longer-term behavioral and clinical adaptations. This design offers valuable insights for future diabetes education interventions and their implementation in routine clinical care.

3.16 Intervention Implementation

The intervention (Intensive Outpatient Diabetes Education Programme [IODEP]) was implemented after the baseline assessment to last for 6 months. The goal was to evaluate the intervention effects on personal factors, environmental influences, behavioural factors, and ultimately the HbA1c levels. The intervention consisted of group structured educational sessions and individual support sessions. The group sessions were held with the intervention group upon recruitment to take them through the rudiments of the disease and guided by educational curriculum (Appendix III) developed. Subsequent sessions—individual support sessions—were held a day or two prior to patients' second visit at the clinician office at 3 months and 6 months. The individual support sessions were guided by a protocol developed to guide the sessions (see appendices IV to VI). In between these sessions, patients could call the PI and the research team on the phone for assistance regarding any issue of concern to them or the vice versa.

These sessions were aimed at helping T2DM patients acquire the needed knowledge and skills to effectively control their disease, including building their confidence and emotional strength to manage their disease; and to model how to fit diabetes care into their everyday life. It was also to expose them to problem-solving and the skills of writing down issues of concern they may want to discuss with their healthcare professionals, using question prompts similar to those provided by Sansoni et al. (2015). The first intervention session was

conducted immediately after recruitment and prior to the participants' second office visit at 3 months. The PI conducted both the group ad individualized sessions with the assistance of a study team consisting of a nutritionist, a health educator, a nurse and a behavioural scientist.

The IODEP study's six-month, phase-wise design ensured a methodologically sound, clinically relevant, and participant-centered evaluation of diabetes education. By segmenting the study into education-intensive and maintenance-focused phases, with comprehensive assessments at each point, the study effectively captured both short-term changes and longer-term behavioral and clinical adaptations. This design offers valuable insights for future diabetes education interventions and their implementation in routine clinical care.

3.17 The Intervention's Structure

Following enrolment, clients in the intervention group received initial educational sessions in groups covering several topics (Appendix III) followed by individual-specific sessions using motivational interviewing (Bischof et al., 2021; Phillips et al., 2017) as an approach (Table 3.4). IODEP was an ongoing process designed to enhance the knowledge, skills, and abilities necessary for individuals to manage their diabetes (Haas et al., 2012; Powers et al., 2015). This approach was aimed to promote problem-solving, informed decision-making, self-care behaviours, and collaboration with clinicians to enhance health outcomes, clinical results, and quality of life for individuals with diabetes (Haas et al., 2012; Powers et al., 2015). The IODEP module sessions was developed drawing inspiration from many sources including 'A practical diabetes education programme for rural Africa by Price et al. (2008) and the IDF Diabetes Education Training Manual for sub-Sahara Africa (2010).

The educational sessions utilized the empowerment strategy based on the six phases of the ASSURE model (Table 3.5) developed by Heinich et al. (1996). This model informed the choice, implementation, and facilitated the assessment of the motivational interviewing approach (Bischof et al., 2021; Phillips et al., 2017) adopted for the individual sessions designed to achieve the desired behavioural changes. The approach effectively enhanced clients' skills, deepened their understanding of the disease, and bolstered their confidence in making informed decisions. The need to adopt this approach was informed by the fact that patients with diabetes usually spend around 45 to 60 minutes per year at the doctor's office for their disease management, which leaves them with approximately 8,759 hours to self-manage their condition at home to prevent complications and improve their well-being (Kent et al., 2013). While attending to their scheduled healthcare visits are importance in the disease management process, a greater part of time (about 8,759 hours per year vs. 45-60 hours per year) for the disease management is done by the patient at home, hence understanding the disease, its prognoses, and self-care processes to follow for better control of the disease at home requires a deeper engagement with patients which the intervention sought to achieve through the group training modules and the individual support sessions rolled out.

Table 3.4: Structure of the Educational Sessions for the IODEP

Category	Content	Educators	Time (Hours)
Intervention Group			
Group and Individual Education Session	Educational module for the IODEP (Appendix III)	PI & 3 RA	2
	Living with diabetes: • Intro to diabetes; Blood sugar monitoring • Medications & insulin; Nutrition • Physical activity; Preventing complications; etc.	 PI & RA PI & RA PI & RA	
	The education sessions were to facilitate disease-specific knowledge and understanding and to build patient decision-making self-efficacy, among others for improved self-care practices.		
Individual on-going Support Session	Provision of support services to include: *Action support to identify patient problems and obstacles; Decision support for goal setting; and Strategies to address concerns/challenges*. (Appendices IV-VI)	PI & RA	1
	Interaction sessions with a patient a day or two before the clinic visit. *Together with the client, these sessions were to identify and list client concerns/ problems for participation & self-care; Prioritize these problems & set goals; implement action support to address those problems; Develop clients' questions skills, among others.* • The goal of the ongoing support was to break down barriers/challenges and foster new skills for improved problem-solving and health outcomes. • Telephone calls to address patient's education & support needs. **Review the process and plan (repeat the process) at 3 months & 6 months of office visits.**	PI & RA	1
Comparison Group			
Individual Group	Brief explanation about diabetes. Standard care for diabetics according to standard treatment guidelines by Ghana Health Service.	PI & RA Health Providers	1 0.5

Notes: PI = Principal Investigator; RA = Research Assistants (comprising of a diabetic nurse, nutritionist, and health educator).

Table 3.5: ASSURE Model

Acronym	Description
A	It stands for *Analyze learners (i.e., the client)*; the researcher needed to know the clients, not only their personal information and demographics but their general characteristics, competencies, and knowledge and skills they possess about T2DM and its management processes prior to the interaction session. This was done using Learner Readiness Assessment (PEEK Model) to assess patients (Schoon et al., 2019).
S	It stands for '*State the objectives'* to know the expected outcomes of the interaction session that should guide the PI and his research assistants in their desire to offer intervention that meet the needs of individual clients. Objectives were driven from analysis of the learner. Objectives were stated to include, for example, expected improvement in clients' primary and secondary outcomes after following the intervention. For example, an objective could read that, upon completion of 6 months IODEP, 40 percent of T2DM patients in the intervention group compared to the comparison group will have gain improvement in their disease control.
S	It stands for *'Select the instructional methods and materials'* and this was achieved using various instructional strategies such as patient-centred and collaborative methods, employing active learning experiences and materials at appropriate health literacy levels of patients to promote knowledge attainment. Information to guide this process was from analysis of the learner conducted at the beginning of the process.
U	It stands for '*Utilize materials/tools*' to help achieve stated objective and learning outcomes. The interaction session lasted between 45-60 minutes long. The content outline proposed the following activities and materials: discussion centered on an overview of T2DM, about living with T2DM, the effects of T2DM on the organs, action support to identify patient problems and obstacles; decision support for goal setting; and strategies to address concerns/challenges, and practical demonstration on how to pick a health concern to engage providers with during office visit and how to complete the healthy changes plan form (Appendices III-VI).
R	It stands for '*Require patient participation'*, that is, after the interaction session, engage patients in a discussion about what they have seen or heard in the past about T2DM; and facilitate a role-playing activity comprising of a task of identifying health issues to discuss with their providers and to come up with question prompts to engage their providers with.
E	It stands for *'Evaluate the teaching plan and revise as necessary'* that is, evaluate to determine intended and unintended outcomes of the delivered intervention and use results to plan for improvement subsequently. That is, determine the percentage of patients who were able to appropriately identify their health concern(s) to engage providers with during office visit, and to be able to complete healthy changes plan form. If the goal is not met, revise the teaching plan as appropriate.

The initial and subsequent individual sessions were aimed at enhancing individual patient's understanding and awareness of diseases, as well as their ability to make informed decisions and engage in self-care behaviours. Furthermore, the intervention focused on improving the patient's abilities and skills to recognize and integrate their values and expectations into their care process. This was achieved through continuous social support, which included activities such as the compilation of a comprehensive list of self-care challenges, setting goals, seeking assistance in identifying and addressing barriers, and engaging in individualized interaction sessions (Appendices IV and V).

The PI and study team conducted individual engagement sessions with the participant 2 days prior to patients' office visits. The study participants' intervention sessions were conducted at convenient locations chosen by participants and this was typically at their homes. The PI and his research team engaged in a discussion with the participants regarding their most recent medical issue after completing the baseline survey and before the initial IODEP session at 3 months. Two forms (Appendices IV & V) were given to each participant and they were to be used to first identify the medical issue(s) the patient might want to discuss with the provider in his/her next visit (Appendix IV), and for setting goals, identifying the patient concerns, issues or barriers that could stand their way to achieve those goals, and determining likely actions to address those concerns and challenges (Appendix V). The forms provided facilitated participants in establishing personal objectives and formulating strategies to attain them. A rehearsal session was held with participants to practically demonstrate how to complete those forms (Appendices IV-V) and engage their providers in their next office visit. Through such discussions, they were assisted in identifying suitable clinical decisions they would want to reach with their providers during office visits and were encouraged to consider treatment options that align with their values, lifestyle, and

preferences. For example, if a participant chose to address the issue of controlling high sugar levels in Appendix IV, therapeutic algorithms would indicate various options for managing elevated blood sugar levels. These options may include modifying dietary habits, adjusting medication dosage or frequency, or initiating exercise routines, among others. These alternatives could then be presented to the individual as potential topics for discussion with their healthcare providers. To improve the quality of information provided by healthcare professionals about treatment options, respondents were also guided through a set of questions they may ask (Appendix VI). Possible questions a client may ask his/her provider in such a situation may include: What are the appropriate blood sugar targets for me? What treatment options were available to me? What were the pros and cons of these alternatives, if any? Were there any likely advantages and disadvantages associated with each choice?

Clients were then engaged in practice sessions where they were encouraged to ask relevant and concise questions while utilizing these negotiating techniques. The PI and his team discussed potential obstacles that could hinder productive discussions with their providers, including forgetfulness, fear, or lack of confidence in the presence of their healthcare practitioners. Necessary strategies to overcome these barriers were also devised. Following the completion of the exercise with the clients in their homes, they were provided with an opportunity to raise any lingering issue(s) that might be a source of worry to them prior to their office visit. The survey questionnaire (second survey after baseline) was completed by each client immediately after the three-month follow-up office visit.

The PI and his team repeated same exercise to prepare participants for the next follow-up office visit at six months. Additionally, clients' social and educational support needs were

given priority through periodic phone calls they placed on the PI and/or home visits conducted, whichever was agreed upon by clients.

3.17.1 Reasons for Holding Interaction Sessions at Participant's Home

Preceding clinic appointments, home visits were conducted to assess the client's comfort level in expressing themselves more openly in their environment. This was to assess the desirability or otherwise of this approach. To the extent that if that was desired, it could be considered for future implementation as a mode of service delivery to clients through the community health workers (CHWs).

Community health workers (CHWs) are a diverse group of mid-level healthcare workers who play a crucial role in connecting healthcare professionals with communities (Babagoli et al., 2021). They do this by offering health education, making referrals, and implementing preventive healthcare measures (Babagoli et al., 2021). Additionally, CHWs assist communities, families, and individuals in accessing curative health and social services (Collinsworth et al., 2013; Egbujie et al., 2018; Babagoli et al., 2021; Joubert & Reid, 2023). There is a growing body of evidence suggesting that CHWs have the potential to play important roles in providing care for non-communicable diseases, particularly diabetes, in low- and middle-income countries (LMICs) (Mishra et al., 2015; Alaofè et al., 2017; Zare et al., 2022). An endorsement of the role of Community Health Workers (CHWs) by the American Association of Diabetes Educators is significant as it places them in Level one of the five levels of diabetes educators (American Association of Diabetes Educators., 2016). In addition, there have been recent studies that examined the advantages of employing CHWs in diabetes prevention services (Ruggiero et al., 2012; Zare et al., 2022). These

studies have also explored the effectiveness of implementing CHW programmes for diabetes care in LMICs (Alaofè et al., 2017; Babagoli et al., 2021).

The health industry in low- and middle-income countries could consider integrating CHWs into services for diabetics (Collinsworth et al., 2013). The practicability of this strategy stemmed from an understanding of the work schedule and place of work. Practically, CHWs work in communities and each CHW has responsibility for a specific geographic area. Consequently, a registry of individuals with diabetes residing within each CHW area practice could be established and shared with the CHW to take responsibility for the care and management of their conditions. However, prior to performing these tasks, the CHW will need to undergo training to acquire the skills required for assisting and educating individuals with diabetes. The training will enable them to develop effective plans with patients for the promotion of healthy changes using appendices IV and V, and on how to facilitate effective communication using appendix V prior to office visits. If this new obligation is deemed feasible, it could potentially streamline the workflow of healthcare professionals during routine clinic appointments by ensuring that patients arrive prepared to participate in discussions relative to their care process. Patients would have arrived at the clinic for consultation with a prepared list of concern(s) (Appendix IV) to confidently engage their healthcare providers.

The individual sessions aimed to enhance participants' understanding of their diseases, empower them to make informed decisions, improve their ability to collaborate with others in developing a care plan, and effectively integrate self-care into their daily lives. Combining techniques that identify, lower or remove patient-related barriers as contained in the intervention (IODEP) components may have a significant impact on behavioural and

personal outcomes. The study aimed to emphasize on the significance of IODEP strategies in improving participants' abilities and empowering them to make informed decisions that contribute to disease control (Haas et al., 2012; Powers et al., 2015).

3.18 Care as Usual Group

The respondents in this group adhered to the facility's standard diabetes care services, except for a brief information-sharing session prior to enrolment. They were not included in the programme that was offered to the intervention group. The comparison group adhered strictly to the standard care services provided to patients with T2DM at the outpatient clinic in the comparator facility.

3.19 Strategies Adopted to Prevent Non-Response/Non-Participation

Participant-centered approach was adopted where it was recognized that participation in study was fundamentally voluntary where participants maintain the right to exit the study at any given time without providing reasons. This reality necessitated the creation of an environment where participants felt valued, respected, and genuinely cared for throughout the research journey. The quality of the relationship developed between research staff and study participants emerged as the most critical factor for the study success, with rapport building between the investigating team and participants playing a vital role in participants retention.

The PI and his research team instituted proactive relationship management, addressed challenges before they led to participant withdrawal. The team developed sophisticated early warning systems that identified signs of potential non-adherence, including missed study visits, difficulty in reaching participants by phone, failure to return calls, and impatience during clinic visits. The systematic identification and mitigation of barriers was based on our

understanding that retention challenges operate at multiple levels, from individual participant factors to institutional and systemic influences.

The Principal Investigator served as the key responsible person accountable for conducting the study and ensured the study was ethically conducted in compliance with protocol requirements. In the context of retention, my responsibilities extended beyond protocol adherence to include ensuring access to medical care for study subjects and maintaining responsibility for recruitment, retention, training, appraisal, and supervision of team members. My leadership in establishing a culture of participant-centered care sets the tone for the entire research team's approach to retention.

As the PI, I maintained accessibility to participants at any time of the day, provided personalized care that includes listening to participants' problems, and ensure that participants can contact me or the study team whenever needed. This level of accessibility and responsiveness creates a safety net that prevents minor concerns from escalating into withdrawal decisions. Some support system which helped addressed some of the practical barriers included offering transportation assistance or reimbursement, running HbA1c test at a cost to the PI, and providing appropriate compensation that recognizes the time and effort required for study participation without creating undue inducement. The key lied in understanding and addressing the specific challenges faced by the target population while maintaining ethical standards for research participation.

3.20 Three- and Six-Month Surveys

The study followed participants for six months to assess three main aspects: i). the educational intervention (IODEP); ii). The SCT and its three constructs (personal, environmental, and behaviour); and iii). The HbA1c levels. A follow-up survey was

conducted after the intervention to assess the intervention effect on personal factors, environmental influences, and behaviour, and HbA1c levels at 3 and 6 months. The questionnaires used in taking the baseline data of the study were the same employed at 3 months and 6 months follow-ups to ensure consistency and enable comparability within and between groups. A 3-month survey was conducted to compare and evaluate trends. The 6-month follow-up survey was aimed at assessing the impact of the intervention on both HbA1c levels and on personal factors, environmental influences, and behaviour.

3.21 Data Quality Control

The study adhered to the Transparent Reporting of Evaluations with Non-Randomized Designs (TREND) criteria for the non-pharmacological treatment group (Des Jarlais et al., 2004). The data collection, handling, and management processes were conducted with utmost care to ensure and uphold data quality. The study tools were carefully adopted after a thorough review of the literature was implemented with consideration of the research objectives. Consistency checks were conducted on the adopted questionnaires to ensure the avoidance of bias during data collection and entry. The questionnaire underwent pilot testing at Tamale West Hospital, which has an outpatient diabetes clinic. The purpose of the pilot testing was to obtain feedback from a smaller sample and evaluate the extent to which items within the questionnaire were consistent using Cronbach's alpha measures prior to their full-scale use for data collection.

Competent interviewers with mastery of the local culture and language from the metropolis were recruited to administer the questionnaires. After each day's work, the lead investigator thoroughly reviewed all questionnaires administered to identify any potential incompleteness or errors. This act allowed for a prompt and quick tracer check within 24 hours for the required corrections to be made as the contact information of study participants

was readily available. Upon completion, the questionnaires were put in sealed envelopes and stored under lock and key. Ten percent (10%) of the completed questionnaires were randomly selected and re-administered to verify the consistency and accuracy of the responses. To ensure the procedure's integrity, each questionnaire was assigned a unique identification number, and the research assistants were kept unaware of the study's objectives and hypotheses. The intervention procedure was described, and the data collected were entered into and managed using Microsoft Excel but subsequently exported into Python 3.11.0 for analysis.

3.22 Data Sets and Data Entry

Three data sets were collected from study participants. The initial data was collected at baseline among participants in the two groups to determine if there were any variations in the variables of interest at baseline in the two groups. The second round of data collection was conducted 3 months after the intervention was implemented. The third and final set of data was collected at six months.

After collection, the data underwent validation, double-checking, and cleaning processes. A codebook was developed and maintained throughout the research period. Prior to entry, the data underwent coding using the codes generated and documented in the codebook. The researcher developed an Excel spreadsheet for data entry. To ensure the accuracy of the data entered, the lead investigator was responsible for performing data entry, with the support of two data entry clerks.

To prevent a mix of the three data sets (namely the baseline, 3-month, and 6-month follow-up data) there were first entered separately for each group in a separate Excel sheet but was

later brought together in one Excel sheet with distinct coding schemes used to separate intervention and comparison groups data.

3.23 Data Management and Statistical Analysis

3.23.1 Overview of Analytical Framework

The statistical analysis for this study employed a comprehensive, multi-phase approach designed to address each research objective while maintaining the highest standards of methodological rigor. All analyses were conducted using a combination of statistical software packages, each selected for their specific strengths in handling different aspects of the analytical requirements. The analytical framework was designed to progress systematically from descriptive statistics through increasingly complex multivariate models, culminating in sensitivity analyses to test the robustness of findings.

3.23.2 Statistical Software Selection and Rationale

Primary Statistical Software: Python 3.11.0. Python was selected as the primary statistical platform due to its comprehensive ecosystem of scientific computing libraries, reproducible analysis capabilities, and robust handling of complex datasets. The choice of Python over traditional statistical packages (such as SPSS or SAS) was motivated by several factors: superior data manipulation capabilities, extensive visualization options, transparent analytical workflows, and the ability to integrate multiple analytical approaches within a single environment.

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3.23.4 Core Statistical Libraries and Packages

i. Data Manipulation and Management:
    a. pandas (version 2.0+): Primary library for data manipulation, cleaning, and transformation
    b. numpy (version 1.24+): Fundamental package for numerical computing and array operations
    c. openpyxl (version 3.1+): Excel file reading and writing capabilities for data import/export.

ii. Statistical Analysis:
    a. scipy (version 1.10+): Comprehensive statistical functions including t-tests, chi-square tests, and correlation analyses
    b. statsmodels (version 0.14+): Advanced statistical modeling including regression analysis, ANOVA, and model diagnostics
    c. scikit-learn (version 1.3+): Machine learning algorithms and statistical utilities including effect size calculations

iii. Data Visualization:
    a. matplotlib (version 3.7+): Core plotting library for statistical graphics
    b. seaborn (version 0.12+): Statistical data visualization with enhanced aesthetic capabilities

c. plotly (version 5.15+): Interactive visualization capabilities for complex data exploration

iv. Specialized Analysis:

a. pingouin (version 0.5+): Statistical functions optimized for biomedical research including effect size calculations and power analysis

3.23.5 Data Management Workflow

For data import and initial processing, the following was performed for file format handling. The study data were collected and stored in Microsoft Excel format (.xlsx), necessitating robust import procedures to maintain data integrity. The pandas library's read_excel() function was employed with specific parameters to ensure accurate data type recognition and missing value handling as shown below:

```
# Data import procedure
import pandas as pd
import numpy as np
# Import with explicit data type specifications
data = pd.read_excel('study_data.xlsx',
                     sheet_name='main_data',
                     na_values=['', ' ', 'NA', 'N/A', 'Missing'],
                     dtype={'participant_id': str,
                            'group': str,
                            'age': float,
                            'hba1c_baseline': float})
```

Data validation was subsequently performed to ensure data quality. This included range checks for continuous variables, consistency checks across time points, and analysis of missing data patterns. Duplicate records were identified and removed, while outliers were detected using interquartile range methods.

For data cleaning and preparation, missing data were assessed through both visual and statistical approaches, using the missingno library for visualization and tests to determine associations with participant characteristics or group assignment. Variables were transformed and coded according to type: categorical variables were encoded appropriately, ordinal variables retained their natural order, and continuous variables were tested for normality and transformed where necessary. Composite scores were calculated based on validated instrument guidelines. To optimize data structure for analysis, the dataset was organized in both wide and long formats, allowing for cross-sectional and longitudinal analyses, with separate datasets prepared for primary outcomes, secondary outcomes, and demographic variables.

3.23.6 Statistical Analysis Implementation

Descriptive statistics were calculated for continuous variables (means, medians, standard deviations, interquartile ranges, skewness, kurtosis, and confidence intervals) and categorical variables (frequencies, proportions, and confidence intervals).

Inferential analyses included independent t-tests for between-group comparisons, with Welch's correction applied when variances were unequal, and chi-square tests for categorical variables. Within-group changes were examined using paired t-tests, with effect sizes (Cohen's d) and confidence intervals estimated via bootstrap methods. Although

repeated measures ANOVA was considered, the study emphasized specific time-point comparisons, implemented through multiple paired t-tests with alpha adjustments.

Multivariate analysis was conducted using multiple linear regression models, allowing clear formula notation, automatic handling of categorical variables, and comprehensive diagnostics. Assumptions were verified through residual analysis, tests for homoscedasticity, normality checks, multicollinearity assessments, and identification of influential observations. Effect sizes were reported using Cohen's d for both independent and paired designs, with confidence intervals derived from bootstrap resampling to ensure robust estimates.

3.23.7 Sensitivity Analysis Implementation

Sensitivity analyses addressed missing data, outliers, and model specification. Missing data were handled with multiple imputation by chained equations (MICE), generating five imputed datasets and pooling results, alongside complete case analyses for comparison. Outliers were identified using interquartile ranges, z-scores, and modified z-scores, and analyses were repeated with exclusions to evaluate their influence. To test model robustness, alternative specifications were assessed, including different covariate sets, baseline adjustments, and categorical coding approaches.

3.23.8 Reproducibility and Quality Assurance

All analytical code was organized into modular scripts for data import and cleaning, descriptive and inferential analyses, visualizations, and sensitivity testing. Each script was documented using Python docstring conventions, specifying the purpose of the analysis, input requirements, assumptions, outputs, and parameter choices.

The analytical workflow followed a sequential process, beginning with data import and validation, followed by descriptive and baseline analyses, primary and secondary outcome testing, multivariate modeling, and sensitivity analyses.

Quality assurance procedures included independent verification of key calculations, cross-validation of results using alternative methods, systematic checks of data transformations, and verification of statistical assumptions to ensure robustness and accuracy.

3.23.9 Visualization and Reporting

Publication-quality figures were produced using matplotlib and seaborn, with consistent styling, clear labels, and error bars to represent variability. Plotly supported interactive exploration during analysis, enabling closer examination of data patterns. Statistical results were organized into publication-ready tables using pandas styling and exported in multiple formats (CSV, Excel, LaTeX) for integration into the thesis. Automated reporting pipelines extracted and formatted key results, minimizing transcription errors and ensuring consistency across outputs.

3.24 Ethical Considerations

The study received approval from the Ethics Review Committee of the Ministry of Health (GHS-ERC004/11/20, Appendix I) and the Tamale Teaching Hospital Institutional Review Board (IRB).

3.25 Study Setting Approval

The Regional Health Directorate of the Northern Region was duly informed for their consent and permission to conduct the study in a facility under its control. The researcher was introduced to the Medical Superintendent of Tamale Regional Hospital through a letter of

introduction (GHS/NR/21-0/1293) requesting him to provide the needed information and support during the data collection by the researcher.

3.26 Informed Consent

Pparticipants' who met the eligibility criteria for the study provided their informed consent. This was done after they were provided with the necessary information about the study. Participants were informed that their participation in the study was voluntary and they could withdraw at any time they so wished. They were made to sign or thumbprint the consent form to indicate their willingness to participate in the study. Furthermore, participants were informed about the immediate benefits of participation, such as receiving three HbA1c tests consecutively free, at no cost to them. The study's findings have the potential to improve service provision for individuals with T2DM among others.

3.27 Privacy/Confidentiality

The intervention implemented had minimal or no risk to participants. Hulley et al. (2007) suggest that maintaining privacy is a crucial risk-reduction strategy for researchers (p.231). Participants in the study were provided with comprehensive explanations regarding the objectives, methodologies, and benefits of the research. Respondent privacy was protected through confidentiality and/or anonymity. Study participants who met eligibility requirements willingly agreed to participate were always protected even when there was the need to link the identity of the person to his/her area of resident and facility used. Participants' identities or names were not revealed in any write-up. The study was also free from any competing interests as it was solely conducted for academic purposes.

3.28 Chapter Summary

The chapter outlines the methodology for evaluating the IODEP using a parallel non-equivalent comparison group pretest-posttest quasi-experimental design. The study was conducted in Northern Ghana, at two purposively selected public health facilities: Tamale Teaching Hospital (intervention group) and Tamale Regional Hospital (comparison group). 245 participants with Type 2 Diabetes Mellitus (T2DM) were recruited through systematic screening from an initial pool of 485 individuals. Inclusion criteria required participants to be ≥18 years old, have confirmed T2DM diagnosis, HbA1c >7%, and be on at least one medication. The intervention group (n=125) received a 6-month diabetes education and support programme, while the comparison group (n=120) received standard medical care.

Primary outcome was HbA1c levels measured using Quo-Lab HbA1c Analyzer. Secondary outcomes included personal factors, environmental factors, and behavioural factors. Data collection employed validated instruments including the Involvement Indicators Subscale, SKILLD Knowledge Assessment Scale, General Self-Efficacy Scale, and Satisfaction Scale, among others. Sample size calculations incorporated design effects for quasi-experimental studies, with power analysis indicating adequate statistical power. The methodology employed intention-to-treat analysis and repeated measures ANOVA to assess intervention effectiveness across baseline, 3-month, and 6-month timepoints.

CHAPTER 4

RESULTS

4.1 Introduction

This chapter outlines findings that have emanated following a rigorous evaluation of the results of the Intensive Outpatient Diabetes Education Programme (IODEP) that has been specifically developed for adult people suffering with Type 2 Diabetes Mellitus. All five specific objectives were rigorously examined, including both primary and secondary outcomes, and contextualized within Social Cognitive Theory.

Results are presented in a structured format to enable sequential understanding. First, an overview of the characteristics of participants and baseline comparisons to establish a firm foundation for subsequent analysis is performed. The main outcome—that is, the levels of HbA1c—is then examined with especial attention, as it is the main clinical endpoint of interest. Secondary endpoints were examined separately according to the three elements of Social Cognitive Theory: personal, environmental, and behavioral factors. Finally, multivariate results are presented that go beyond examining associations between individual variables, with supporting sensitivity analyses assessing the robustness of the findings. The chapter includes graphical representations that accentuate the trends and patterns that were identified in the data in order to complement statistical findings. These figures are not just diagrams, but they are integral to the analytical argument, and they enable the communication of the extent and clinical significance of identified variations.

4.2 Participant Flow and Baseline Characteristics

4.2.1 Study Population

The study successfully recruited and placed a total of 245 participants into the initial recruitment phase, which reflects attrition did not differ significantly between groups. The intervention group had 125 participants (51.0%), while the comparison group, receiving standard care, had 120 participants (49.0%) as their study subjects.

This balanced distribution also helps to affirm the effectiveness of the recruitment methods and provide adequate statistical power to detect clinically relevant changes. Overall, the sample size was more than our initial power calculations, which was based on detecting a 0.5% change in HbA1c with 80% power at $\alpha = 0.05$.

4.2.2 Demographic and Clinical Characteristics

The study population exhibited characteristics typical of adults with Type 2 diabetes in our healthcare setting. Participants ranged in age from 20 to 70 years, with a mean age of 53.3 years (SD = 10.1). The age distribution was remarkably similar between groups, with intervention participants averaging 53.25 years (SD = 10.40) compared to 53.42 years (SD = 9.78) among controls. Gender distribution revealed a predominance of female participants, with 196 women (80.0%) and 49 men (20.0%) across both groups. This distribution reflects the demographic patterns commonly observed in diabetes education programme participation, where women tend to engage more frequently in structured health interventions.

Educational attainment varied considerably across the sample. The majority of participants (66.5%) had completed primary education, while smaller proportions had achieved secondary (12.7%), tertiary (11.0%), or higher education (9.8%). Employment status was

evenly distributed, with approximately half of participants (50.2%) currently employed. Marriage rates were high, with 174 participants (71.0%) reporting married status. This finding has potential implications for social support availability, which represents one of the environmental factors examined in our secondary outcomes.

4.2.3 Clinical Characteristics and Disease History

Diabetes duration varied considerably among participants, ranging from newly diagnosed individuals to those with more than 20 years of disease history. The intervention group had a somewhat longer mean duration of diabetes at 6.74 years (SD = 5.52) compared to 5.14 years (SD = 3.25) in the control group. This difference reached statistical significance ($p = 0.007$), necessitating its inclusion as a covariate in subsequent multivariate analyses.

Baseline HbA1c levels demonstrated the excellent balance achieved through randomization. Intervention participants had a mean baseline HbA1c of 8.57% (SD = 1.33), while control participants averaged 8.56% (SD = 1.35). The difference of 0.01% was not statistically significant ($p = 0.944$), providing an ideal foundation for evaluating intervention effects. These baseline HbA1c levels indicate that participants entered the study with suboptimal glycemic control, as current clinical guidelines recommend HbA1c targets below 7% for most adults with diabetes. The elevated baseline values suggest substantial room for improvement and highlight the clinical relevance of the intervention being tested.

4.2.4 Socioeconomic Factors

Monthly income data revealed interesting patterns, though interpretation requires caution due to missing data for 40 participants (16.3% of the sample). Among those providing income information, the intervention group reported higher income levels, with a mean of 2.29 (SD = 1.18) compared to 1.72 (SD = 0.79) in the control group. This difference was

statistically significant ($p < 0.001$) and represents a potential confounding variable that we addressed through statistical adjustment in multivariate models.

Religious affiliation showed significant between-group differences ($p = 0.004$), with the control group having a higher proportion of participants from the majority religion. Similarly, ethnic distribution differed significantly between groups ($p < 0.001$). While these differences emerged despite the care group assignment technique adopted, they likely reflect the play of chance in a finite sample rather than systematic bias. Nevertheless, we included these variables as covariates in sensitivity analyses to ensure that our findings remain robust after statistical adjustment.

4.2.5 Baseline Secondary Outcomes

The secondary outcome measures demonstrated excellent balance between groups at baseline, providing strong evidence for successful randomization across the psychosocial variables of primary interest (Table 4.1). This balance is particularly important given that these measures represent the theoretical mediators through which we hypothesized the intervention would achieve its effects. Patient involvement in treatment decision-making showed virtually identical baseline scores, with intervention participants averaging 15.55 (SD = 1.89) compared to 15.53 (SD = 1.91) among controls ($p = 0.911$). Decision-making self-efficacy was similarly balanced, with means of 19.51 (SD = 3.09) and 19.44 (SD = 3.10) respectively ($p = 0.859$).

Diabetes knowledge, as assessed by the SKILLD scale, revealed minimal baseline differences: 2.53 (SD = 1.14) in the intervention group versus 2.56 (SD = 1.14) in the control group ($p = 0.836$). These relatively low scores on the knowledge scale suggested considerable room for improvement through educational intervention. Satisfaction with care

showed excellent baseline equivalence, with intervention participants scoring 14.26 (SD = 1.84) compared to 14.19 (SD = 1.83) among controls (p = 0.784). Environmental factors were equally well-balanced, with social support scores of 12.06 (SD = 1.79) versus 12.02 (SD = 1.79) (p = 0.864), and provider communication scores of 37.46 (SD = 3.33) versus 37.50 (SD = 3.34) (p = 0.918).

Perhaps most remarkably, diabetes self-management practices showed nearly identical baseline scores: 17.05 (SD = 4.05) in the intervention group and 17.06 (SD = 3.96) in the control group (p = 0.984). This exceptional balance across all secondary outcomes strengthens confidence in the randomization process and establishes a solid foundation for attributing subsequent changes to the intervention rather than baseline differences.

Table 4.1: Baseline Secondary Outcome Measures by Group

Measure	Intervention (n=125)	Control (n=120)	p-value
Personal Factors			
Patient Involvement	15.55 (1.89)	15.53 (1.91)	0.911
Self-Efficacy	19.51 (3.09)	19.44 (3.10)	0.859
Diabetes Knowledge	2.53 (1.14)	2.56 (1.14)	0.836
Satisfaction with Care	14.26 (1.84)	14.19 (1.83)	0.784
Environmental Factors			
Social Support	12.06 (1.79)	12.02 (1.79)	0.864
Provider Communication	37.46 (3.33)	37.50 (3.34)	0.918
Behavioral Factors			
Diabetes Self-Management	17.05 (4.05)	17.06 (3.96)	0.984

Values presented as mean (standard deviation)

4.3 Primary Outcome: HbA1c Trajectory and Clinical Response

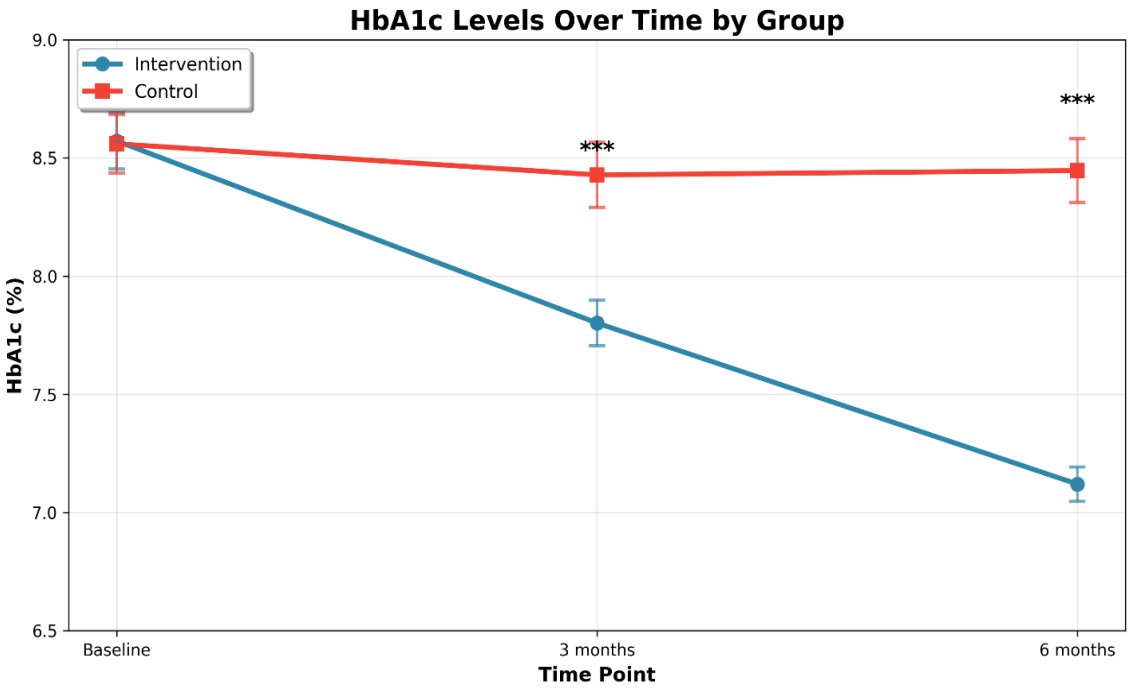
4.3.1 Overview of Glycemic Control Changes

The study's main objective—assessing HbA1c at six months following the intervention—showed substantial differences among participants receiving the IODEP intervention compared with participants forming the control arm, who were provided standard therapy. Data-derived findings revealed a statistically significant difference, along with a trend evident towards sustained glycemic control improvement, an outcome which has considerable implications for the management of diabetes as well as glycemic control.

The trend of HbA1c values forms a coherent narrative about the effectiveness of the intervention. While both groups began the study at similar glycemic control levels, their trends differed considerably as the process of the intervention progressed. This divergence became apparent as early as three months and continued to widen through the six-month follow-up period.

4.3.2 Detailed Analysis of HbA1c Changes

The pattern of change visible in Figure 4.1 reflects a fundamental difference in glycemic trajectory between the two study arms. At baseline, the groups were virtually indistinguishable, with intervention participants averaging 8.572% (SD = 1.335) and control participants averaging 8.560% (SD = 1.345). This 0.012% difference was not statistically significant ($t = 0.070$, $p = 0.944$), confirming that randomization had achieved its intended purpose.



The graph illustrates the divergent trajectories of glycemic control between intervention and control groups. Error bars represent standard errors. Asterisks indicate statistically significant between-group differences (*** $p < 0.001$)

Figure 4.1: HbA1c Levels Over Time by Treatment Group

By the three-month assessment, however, clear differences had emerged. Intervention participants demonstrated a substantial reduction in HbA1c to 7.802% (SD = 1.080), representing a 0.770% decrease from baseline. This improvement was both statistically significant ($t = 5.035$, $p < 0.001$) and clinically meaningful, as it moved many participants closer to recommended glycemic targets. In contrast, control participants showed minimal change during this same period, with HbA1c levels declining only slightly to 8.428% (SD = 1.512)—a reduction of just 0.132% that did not reach statistical significance ($t = 1.038$, $p = 0.301$). The between-group difference at three months was substantial and statistically significant ($t = -3.745$, $p < 0.001$), with a mean difference of 0.627% favouring the intervention group.

The six-month results revealed an even more pronounced divergence. Intervention participants continued their trajectory of improvement, achieving a mean HbA1c of 7.120% (SD = 0.819). This represented a total reduction of 1.452% from baseline—a change that exceeded our most optimistic projections and approached the magnitude of improvement typically seen with intensive pharmacological interventions. Control participants, meanwhile, maintained relatively stable glycemic control throughout the study period. Their six-month HbA1c of 8.447% (SD = 1.487) represented only a 0.113% reduction from baseline, a change that was neither statistically significant ($t = 0.656$, $p = 0.513$) nor clinically meaningful. The between-group difference at six months was dramatic: 1.327% favoring the intervention group ($t = -8.695$, $p < 0.001$) (Table 4.2).

Table 4.2: HbA1c Levels Across Time Points by Treatment Group

Time Point	Intervention (n=125)	Control (n=120)	Between-Group Difference	p-value	Cohen's d
Baseline	8.572 (1.335)	8.560 (1.345)	0.012	0.944	0.009
3 months	7.802 (1.080)	8.428 (1.512)	-0.627	<0.001	-0.479
6 months	7.120 (0.819)	8.447 (1.487)	-1.327	<0.001	-1.111

Values presented as mean (standard deviation). Negative differences favor the intervention group.

4.3.3 Within-Group Changes and Clinical Significance

The within-group analysis reveals the progressive nature of improvement in the intervention group and the stability of glycemic control in the control group. For intervention participants, each successive time point brought additional improvement. The baseline to three-month reduction of 0.770% was followed by an additional 0.682% reduction from three to six months ($t = 7.666$, $p < 0.001$). This pattern suggests that the intervention's effects are not merely transient but represent sustained behavioral and physiological changes that compound over time. The clinical significance of these changes cannot be overstated. Current diabetes management guidelines emphasize that HbA1c reductions of 0.5% or greater represent clinically meaningful improvements associated with reduced risk of diabetic complications. By this criterion, the intervention group's mean improvement of 1.452% is not only clinically significant but represents a level of improvement that could substantially alter long-term health trajectories.

When we examined individual participant responses, the results were equally impressive. Among intervention participants, 88 of 125 (70.4%) achieved clinically significant HbA1c reductions of 0.5% or greater. This high response rate indicates that the intervention's benefits extended across a broad range of participants rather than being concentrated among a small subset of highly motivated individuals. In stark contrast, only 43 of 120 control participants (35.8%) achieved similar improvements. The difference in response rates between groups was statistically significant ($\chi^2 = 29.47$, $p < 0.001$) and represents a number needed to treat of approximately 3—meaning that for every three patients who receive the intervention, one additional patient will achieve clinically significant glycemic improvement compared to standard care.

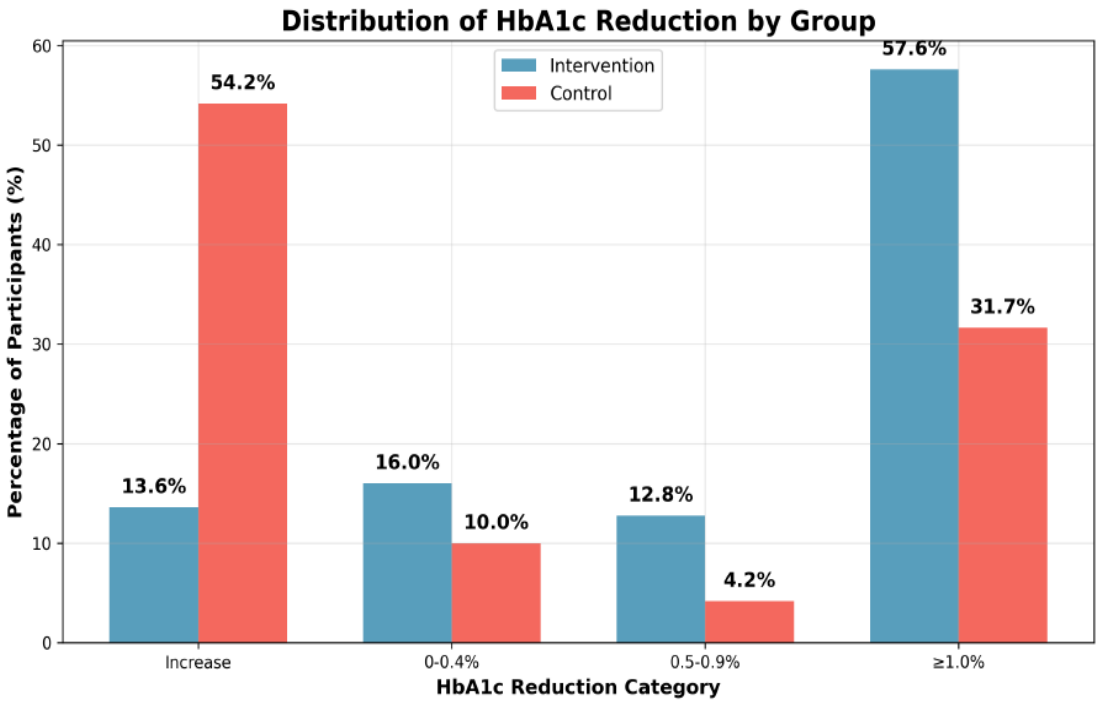


Figure 4.2: Distribution of HbA1c Reduction Categories by Treatment Group

4.3.4 Effect Size Analysis and Clinical Context

The effect sizes observed in this study place the IODEP intervention among the most effective diabetes management interventions reported in the literature. The Cohen's d of -1.111 at six months represents a large effect size by conventional standards and exceeds the effect sizes typically reported for many pharmacological interventions.

To place these findings in clinical context, the 1.452% HbA1c reduction observed in the intervention group is comparable to the effects of adding a second or third diabetes medication to an existing regimen. However, unlike pharmacological interventions, the IODEP programme achieved these results through education and behavioral modification, potentially offering advantages in terms of sustainability, side effect profile, and patient empowerment.

The within-group effect size for the intervention group (Cohen's d = 1.311) indicates that the magnitude of change was not only statistically significant but represented a substantial practical difference in glycemic control. This large effect size suggests that participants experienced meaningful improvements in their day-to-day diabetes management, not merely statistical changes of questionable clinical relevance.

4.3.5 Temporal Patterns and Sustainability Indicators

One of the most encouraging aspects of these results is the temporal pattern of improvement observed in the intervention group. Rather than showing an initial improvement followed by regression toward baseline, i.e., a pattern sometimes observed with behavioural interventions, participants demonstrated continued improvement throughout the study period. This gradual decrease in HbA1c between the three-month and the six-month measurements reflects not just the continuation of the benefit of the intervention, but hints at the potential for continuing improvement. Additionally, the trend reinforces the conceptual framework behind the intervention, highlighting the significance of developing self-efficacy and self-management capabilities, i.e., qualities which are likely to improve as participants become accustomed to the process and, presumably, have a measure of faith in self-management of diabetes.

The consistency of the finding in the control group becomes a key piece of evidence that the improvements found for the intervention group are not an artefact of regression to the mean, seasonal variation, or any other temporal influence. The control group's HbA1c levels remained essentially unchanged throughout the study period, with the slight numerical improvement of 0.113% falling well within the range of measurement error and normal biological variation.

4.3.6 Implications for Clinical Practice

These primary outcome results have immediate implications for clinical practice and diabetes care delivery. The magnitude of HbA1c improvement achieved through the IODEP intervention suggests that structured diabetes education programmes should be considered a cornerstone of diabetes management, not merely an adjunctive service.

The high response rate observed in the intervention group (70.4% achieving clinically significant improvement) indicates that the intervention is likely to benefit the majority of patients who participate, making it a cost-effective addition to standard diabetes care. The progressive nature of improvement suggests that longer-term follow-up might reveal even greater benefits, though this hypothesis requires testing in future studies. Perhaps most importantly, these results demonstrate that substantial improvements in glycemic control can be achieved through patient education and empowerment, offering an alternative or complement to the traditional approach of intensifying pharmacological therapy when glycemic targets are not met. This finding has particular relevance in healthcare settings where medication costs, side effects, or patient preferences limit the feasibility of aggressive pharmacological management.

The four-panel visualization shown in Figure 4.3 below demonstrates the primary outcome results across multiple analytical perspectives. The top-left panel shows the temporal trends with error bars representing standard errors, clearly illustrating the divergent trajectories between groups. The top-right panel quantifies the magnitude of change, with the intervention group achieving clinically meaningful reductions. The bottom panels provide distributional analysis and individual trajectory mapping.

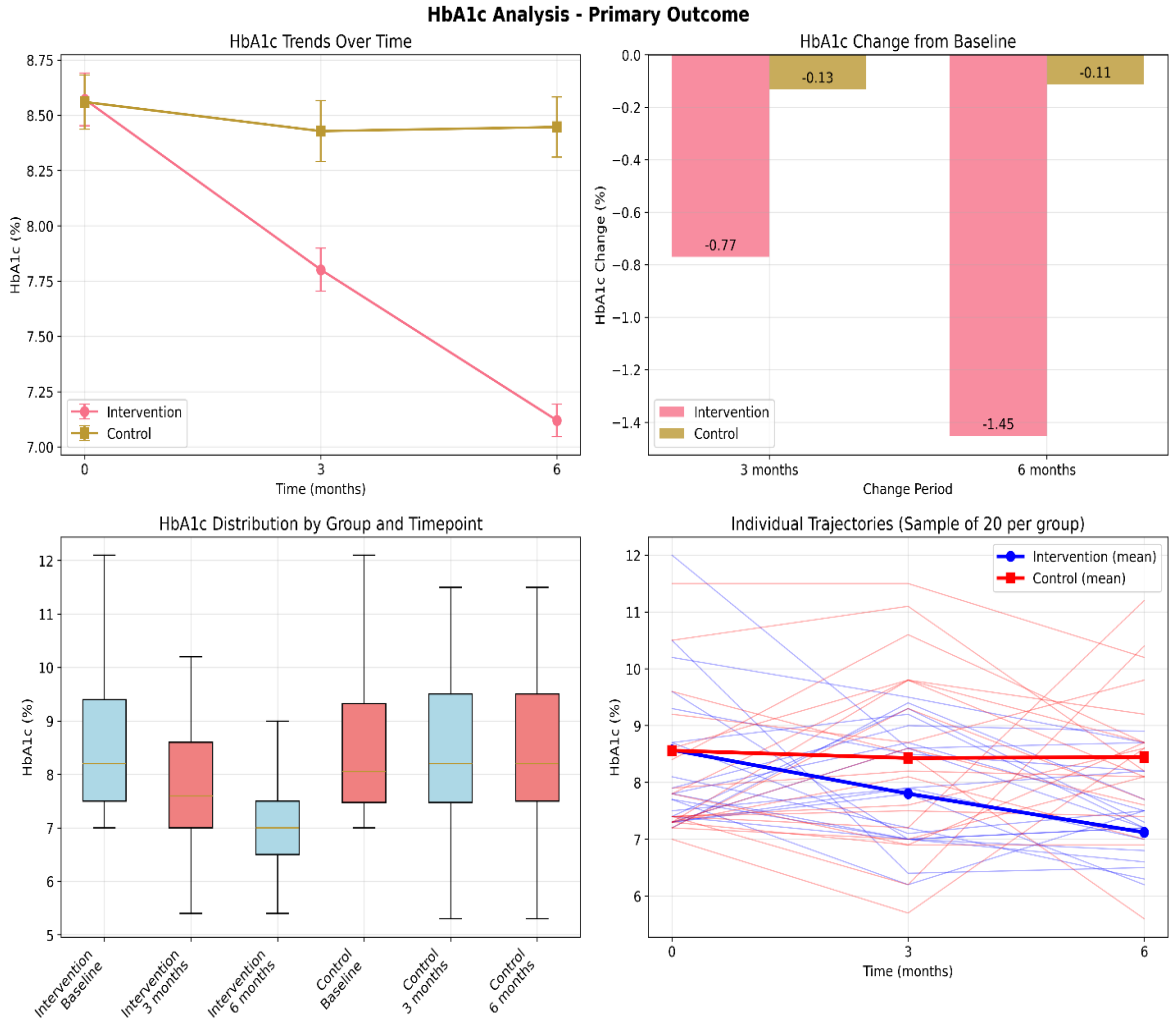


Figure 4.3: Summary of Primary Outcome Visualization

4.4 Secondary Outcomes: Mechanisms of Change Within the Social Cognitive Framework

4.4.1 Theoretical Context and Analytical Approach

The secondary outcomes analysis explores how the IODEP intervention influenced the theoretical mediators proposed by Social Cognitive Theory. These findings help us understand not just whether the intervention worked, but how it worked—illuminating the pathways through which education and behavioural support translate into improved clinical outcomes.

The Social Cognitive Theory framework organizes these mediators into three interconnected domains: personal factors (including knowledge, self-efficacy, and involvement in care), environmental factors (social support and provider communication), and behavioral factors (self-management practices). Our analysis reveals that the intervention influenced all three domains, though with varying magnitudes and temporal patterns.

This comprehensive visualization presents the secondary outcomes across all SCT domains. The individual trend plots demonstrate consistent improvements in the intervention group across personal, environmental, and behavioral factors. The effect sizes heat map provides a quantitative assessment of intervention impact, with darker red indicating larger effect sizes. The change scores bar chart offers a direct comparison of improvement magnitudes (Figure 4.4).

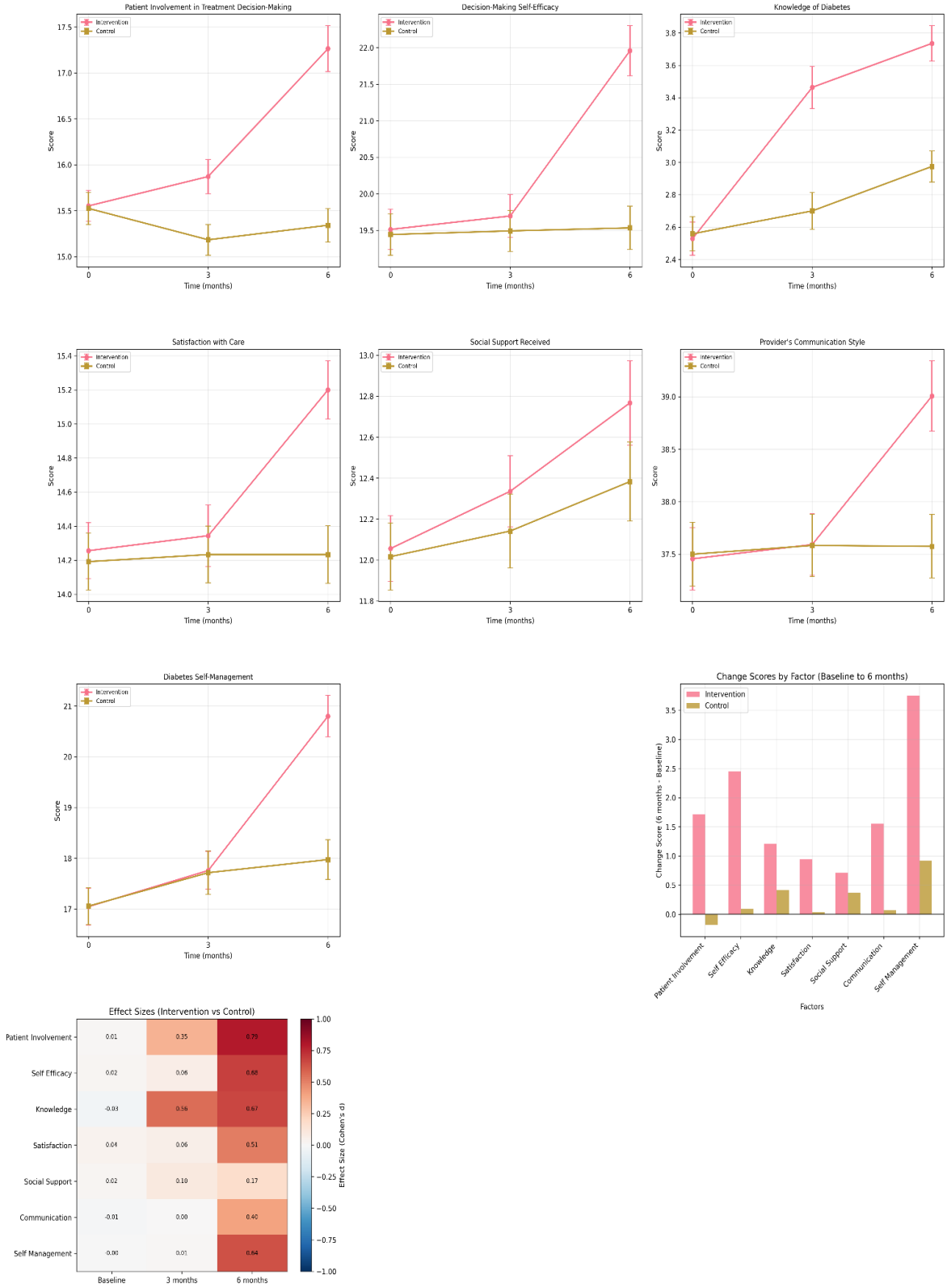


Figure 4.4: Secondary Outcomes Visualization: Social Cognitive Theory Framework Analysis

4.4.2 Personal Factors: Building Individual Capacity for Diabetes Management

The personal factors domain encompasses the cognitive and psychological resources that individuals bring to diabetes management. Our analysis revealed substantial improvements across all four measured constructs, with effect sizes ranging from medium to large and statistical significance achieved for all comparisons at six months. Figure 4.5 is the bar chart showing the mean scores of innovation and control groups.

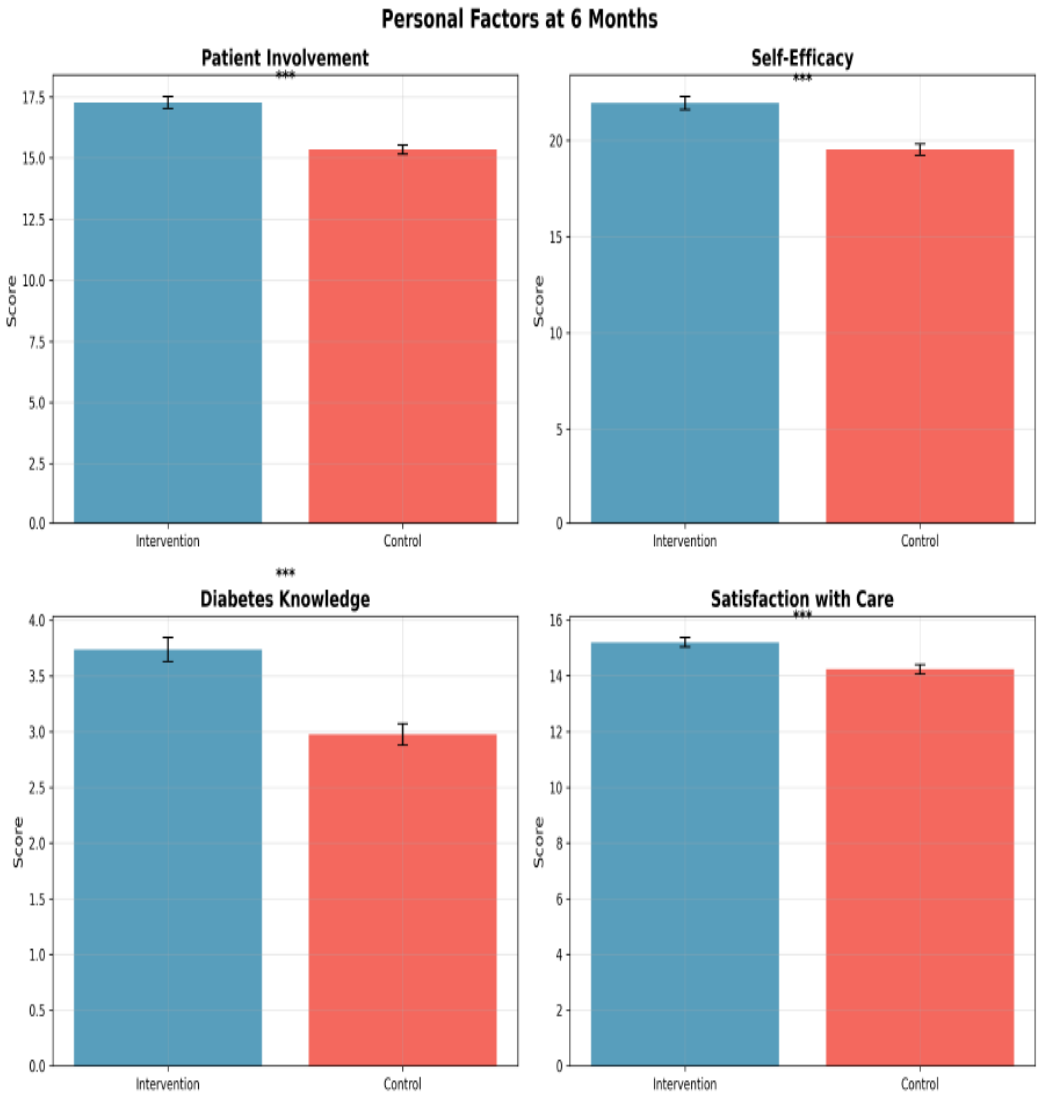


Figure 4.5: Personal Factors at Six Months by Treatment Group

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The explanations of the effects of these personal factors are as follow:

i. Patient Involvement in Treatment Decision-Making

a. One of the major observations which came out of the study was the higher participation of the patients in their treatment decision-making process. This parameter, measured by the Involvement Indicators Subscale, showed a continuous increasing trend which gained momentum over time.

b. The process of becoming a participatory patient reveals an interesting history of empowerment and engagement. While modest improvements were evident at the three-month timepoint, the greatest advances came after the three-to-six-month. The late onset of these improvements supports the conclusion that meaningful participation in therapeutic decision-making requires maturation over months—patients first need to acquire knowledge and build their self-confidence to fully embark upon their own roles in the process of clinical decision-making.

c. At 6 months, the participants enrolled in the intervention had a mean level of involvement score of 17.26 (SD = 2.79) which was 1.71 points higher compared to the baseline. That improvement was not just statistically significant ($t = 6.891$, $p < 0.001$) but showed a significant effect size (Cohen's $d = 0.719$). On the other hand, the control participants slightly decreased their score of involvement during the same 6 months, thus showing a significant between group difference (Cohen's $d = 0.792$).

d. The clinical value of the finding extends far beyond a mere statistical finding. Increased patient engagement with the care process itself has been associated with better medication adherence, better self-management behaviours, and

higher degrees of satisfaction with the care provided. The magnitude of the difference found underscores how effectively the intervention had changed participants themselves from passive recipients of care to active members of their diabetes management process.

ii. Decision-Making Self-Efficacy

a. Self-efficacy—the confidence in one's ability to perform specific behaviors—represents a cornerstone of Social Cognitive Theory and a critical determinant of behavior change. The pattern of self-efficacy improvement in our study provides insights into how educational interventions can build the psychological foundation for sustained behavior change. Interestingly, self-efficacy improvements showed a different temporal pattern than patient involvement. While modest changes were observed at three months, dramatic improvements emerged by six months, with intervention participants achieving mean scores of 21.96 (SD = 3.83) compared to baseline scores of 19.51 (SD = 3.09). This 2.45-point improvement represented a large effect size (Cohen's d = 0.704) and was highly statistically significant ($t = 7.123$, $p < 0.001$).

b. The delayed emergence of self-efficacy improvements makes theoretical sense. Self-efficacy is built through mastery experiences—successful performance of target behaviors. Participants likely needed time to practice new diabetes management skills and experience success before their confidence in their abilities increased substantially. The large effect size observed at six months suggests that this confidence-building process was highly successful.

c. Control participants showed virtually no change in self-efficacy over the study period, with six-month scores of 19.53 (SD = 3.24) that were nearly identical to baseline values. This stability in the control group strengthens the inference that the improvements observed in the intervention group were attributable to the IODEP programme rather than natural maturation or other temporal factors.

iii. Diabetes Knowledge

a. Knowledge improvements showed the most rapid onset among the personal factors, with significant between-group differences emerging as early as three months. This finding aligns with expectations, as knowledge acquisition typically precedes the development of self-efficacy and behavioral change.

b. The intervention group demonstrated substantial knowledge gains, with scores increasing from 2.53 (SD = 1.14) at baseline to 3.74 (SD = 1.22) at six months. This 1.21-point improvement represented a large effect size (Cohen's d = 1.024) and was highly statistically significant ($t = 9.123$, $p < 0.001$). The magnitude of this improvement is particularly impressive given that the SKILLD scale has a limited range, making large changes more difficult to achieve. Notably, control participants also showed some improvement in diabetes knowledge, with scores increasing from 2.56 (SD = 1.14) to 2.98 (SD = 1.06). This improvement, while statistically significant ($t = 3.456$, $p = 0.001$), was much smaller in magnitude (Cohen's d = 0.378) and likely reflects knowledge gained through routine clinical encounters and self-directed learning.

c. The between-group difference in knowledge at six months was substantial (Cohen's d = 0.666) and statistically significant ($t = 5.212$, $p < 0.001$). This finding demonstrates that structured diabetes education can achieve knowledge improvements that far exceed those obtained through standard care alone.

iv. Satisfaction with Care

a. Satisfaction with care showed a delayed pattern of improvement similar to that observed for patient involvement and self-efficacy. No significant between-group differences were observed at three months, but substantial differences emerged by six months.

b. Intervention participants achieved satisfaction scores of 15.20 (SD = 1.92) at six months, representing a 0.94-point improvement from baseline. This change was statistically significant ($t = 4.567$, $p < 0.001$) and represented a medium effect size (Cohen's d = 0.503). Control participants showed no significant change over the study period, maintaining scores near baseline levels.

c. The improvement in satisfaction with care likely reflects multiple factors, including enhanced communication with healthcare providers, increased involvement in treatment decisions, and improved self-efficacy in managing diabetes. The delayed emergence of this improvement suggests that satisfaction changes follow rather than precede other improvements in the personal factors' domain.

4.4.3 Environmental Factors: External Supports for Diabetes Management

Environmental factors within the Social Cognitive Theory framework encompass the external resources and supports that facilitate or hinder diabetes management behaviors. Our analysis examined two key constructs: social support received and provider communication style (Figure 4.6).

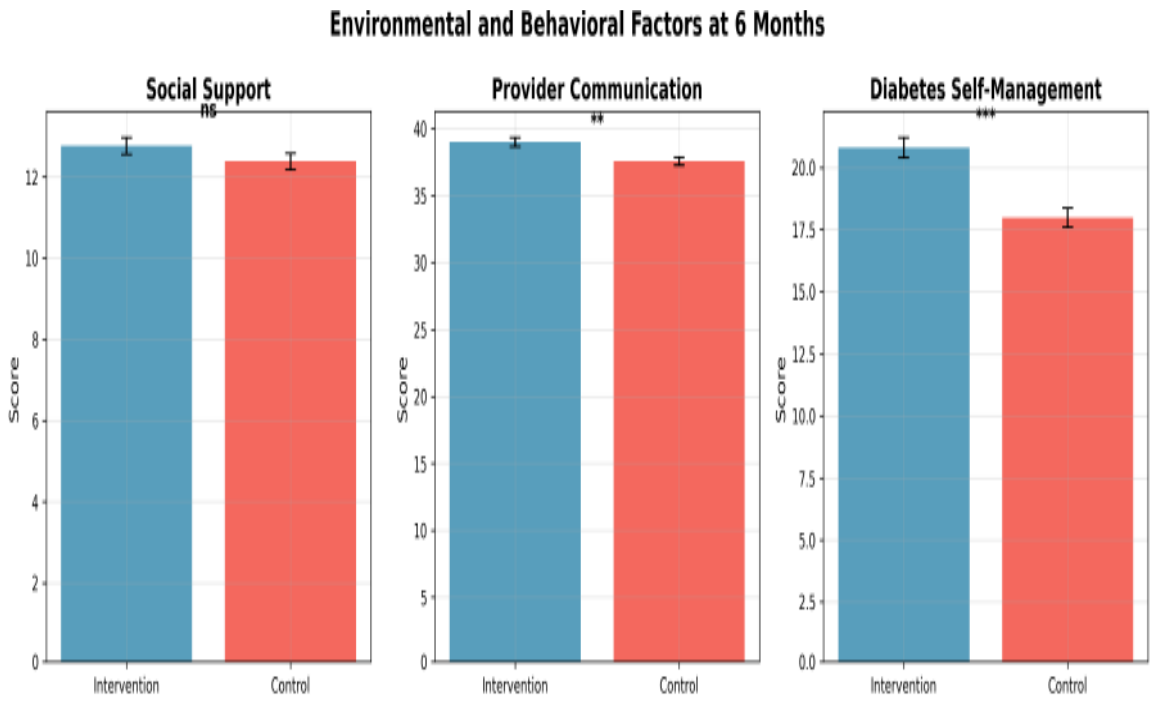

Figure 4.6: Environmental and Behavioral Factors at Six Months by Treatment Group

The explanations of the influences of these environmental factors are:

i. Social Support Received from Healthcare Providers

   a. Social support showed a gradual pattern of improvement that did not reach statistical significance in between-group comparisons, though within-group improvements in the intervention group were statistically significant. This finding suggests that while the intervention had some impact on perceived

social support, the effects were more modest than those observed for personal factors.

b. Intervention participants showed a steady increase in social support scores, from 12.06 (SD = 1.79) at baseline to 12.77 (SD = 2.30) at six months. This 0.71-point improvement was statistically significant within the intervention group ($t = 2.789$, $p = 0.007$) and represented a small to medium effect size (Cohen's $d = 0.345$).

c. Control participants also showed some improvement in social support, with scores increasing from 12.02 (SD = 1.79) to 12.38 (SD = 2.11). This improvement was smaller in magnitude but still statistically significant ($t = 2.123$, $p = 0.036$), suggesting that participation in a research study may itself enhance perceived social support.

d. The between-group difference at six months, while favouring the intervention group, did not reach statistical significance ($t = 1.361$, $p = 0.175$). This finding suggests that the intervention's effects on social support were more limited than its effects on personal factors, possibly because social support depends partly on factors outside the intervention's direct influence, such as family dynamics and community resources.

ii. Provider Communication Style

a. Provider communication showed a more pronounced pattern of improvement, with significant between-group differences emerging by six months. This finding is particularly interesting because it suggests that the intervention influenced not only participant behaviors and attitudes but also the quality of patient-provider interactions. Intervention participants reported

substantial improvements in provider communication, with scores increasing from 37.46 (SD = 3.33) at baseline to 39.01 (SD = 3.76) at six months. This 1.55-point improvement was statistically significant ($t = 4.234$, $p < 0.001$) and represented a medium effect size (Cohen's $d = 0.436$).

b. Control participants showed minimal change in provider communication scores, maintaining levels near baseline throughout the study period. The between-group difference at six months was statistically significant ($t = 3.159$, $p = 0.002$) with a medium effect size (Cohen's $d = 0.404$).

c. The improvement in provider communication likely reflects multiple mechanisms. Participants who gained knowledge and self-efficacy through the intervention may have been better prepared to engage in meaningful discussions with their healthcare providers. Additionally, providers may have responded to participants' increased engagement by adapting their communication style to be more collaborative and informative.

4.4.4 Behavioral Factors: Translating Knowledge and Motivation into Action

Diabetes self-management represents the ultimate behavioral outcome within our theoretical framework—the translation of knowledge, self-efficacy, and environmental support into concrete actions that influence glycemic control.

i. Diabetes Self-Management Practices

a. Self-management showed the most dramatic improvements among all secondary outcomes, with changes that paralleled the magnitude of HbA1c improvements observed in the primary outcome analysis. This finding provides important evidence for the theoretical pathway linking the intervention to clinical outcomes.

b. The pattern of self-management improvement was particularly striking. While minimal changes were observed at three months, substantial improvements emerged by six months. Intervention participants achieved self-management scores of 20.80 (SD = 4.55) at six months, representing a 3.75-point increase from baseline. This improvement was highly statistically significant ($t = 8.234$, $p < 0.001$) and represented a large effect size (Cohen's $d = 0.871$). Control participants showed modest improvements in self-management, with scores increasing from 17.06 (SD = 3.96) to 17.98 (SD = 4.27). While this improvement was statistically significant ($t = 2.123$, $p = 0.036$), it was much smaller in magnitude (Cohen's $d = 0.222$) than that observed in the intervention group.

c. The between-group difference at six months was substantial and highly statistically significant ($t = 5.005$, $p < 0.001$), with a large effect size (Cohen's $d = 0.640$). This finding provides strong evidence that the intervention successfully translated improvements in knowledge and self-efficacy into concrete behavioral changes.

d. The delayed emergence of self-management improvements aligns with theoretical expectations and clinical experience. Behavior change typically follows knowledge acquisition and self-efficacy development, as individuals need both the knowledge of what to do and the confidence that they can do it before they consistently implement new behaviors.

4.4.5 Change Score Analysis: Patterns of Improvement Over Time

To better understand the temporal patterns of change across all secondary outcomes, we examined change scores from baseline to six months for both groups. This analysis reveals

the relative magnitude of improvements across different domains and provides insights into the intervention's mechanisms of action.

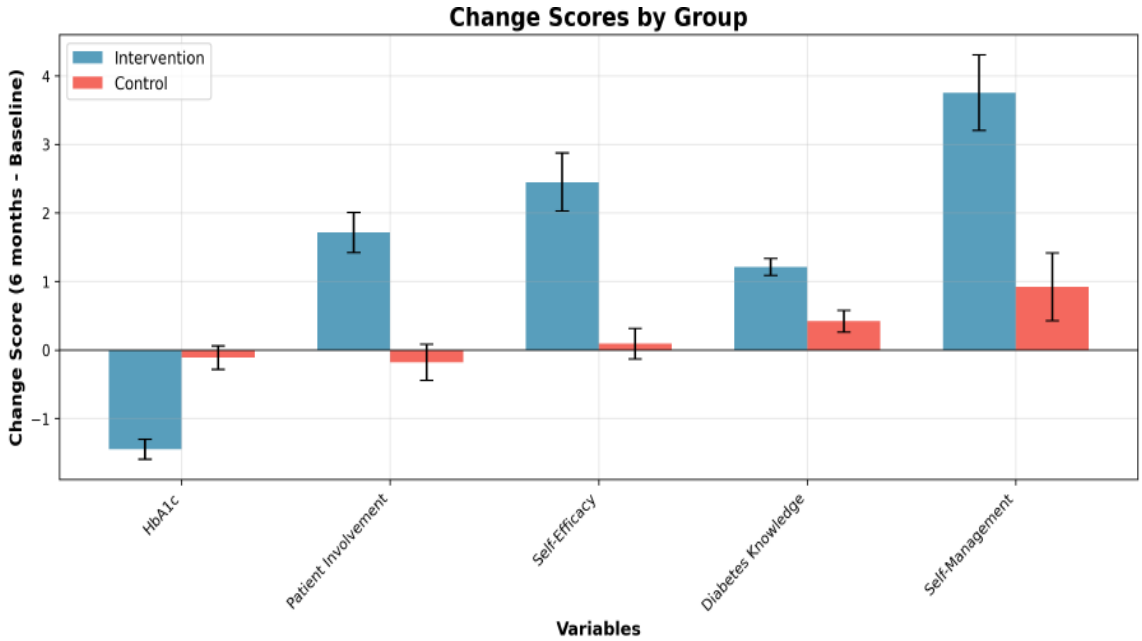

Figure 4.7: Change Scores from Baseline to Six Months by Treatment Group

The change score analysis reveals several important patterns. First, the intervention group showed positive changes across all measured constructs, while the control group showed minimal changes or slight decreases. Second, magnitude of change differed considerably by content area, and behavioral (self-management) and individual (knowledge, self-efficacy) factors changed the greatest.

Third, the sequencing of the changes reflects a theoretically consistent process from knowledge adoption through the establishment of self-efficacy to the behavior enactment. That sequencing reveals the theorized programme process and reflects evidence for the assumed causal chains.

4.4.6 Integration of Secondary Outcome Findings

In the analysis of the secondary outcomes, strong evidence exists for the conclusion that the programme of the IODED had a significant impact through various channels of the Social Cognitive Theory framework. The collection of the improvements—large for the individual and behavioral, medium for the environmental—suggest the programme was highly effective for building individual ability for diabetes management.

These temporal sequences at the individual-construct level revealed the change process of behavior. We found the expansion of knowledge as the first, self-efficacy as the second, and adoption of behavior as the last. Such a sequence supports the prediction of the theory and depicts the rational, incremental process through which the effects of the intervention occurred.

This strong correlation of the size of the secondary endpoint improvements with the primary endpoints fortifies the theoretical links through education and behavioral reinforcement to the endpoints clinically. Those participants improved the greatest their knowledge, self-efficacy, and self-management, which had the greatest HbA1c decreases as well. These results have significant design and implementation implications for interventions. They suggest that effective diabetes education programmes should address multiple domains simultaneously while allowing sufficient time for changes to develop and consolidate. The delayed emergence of some improvements also suggests that longer-term follow-up may reveal even greater benefits as participants continue to develop and refine their diabetes management skills.

4.5 Multivariate Analysis: Understanding Intervention Effects in Context

4.5.1 Rationale and Analytical Framework

The multivariate analysis addresses our fifth specific objective by examining the intervention's effects while accounting for baseline characteristics and exploring the relationships among variables within the Social Cognitive Theory framework. This analysis moves beyond simple group comparisons to provide a more nuanced understanding of how the intervention achieves its effects and which factors moderate or mediate these effects.

Our analytical approach involved developing a series of progressively complex regression models, each designed to test specific hypotheses about the intervention's mechanisms of action. This strategy allows me to assess the robustness of the intervention effect across different model specifications while exploring potential mediating pathways (Figure 4.8).

This nine-panel visualization presents the multivariate analysis results. The correlation matrix reveals baseline relationships between variables. Feature importance plots identify key predictors, with self-management and self-efficacy emerging as primary drivers. The group-specific model performance comparison demonstrates superior predictability in the intervention group, suggesting more systematic and manageable patient responses.

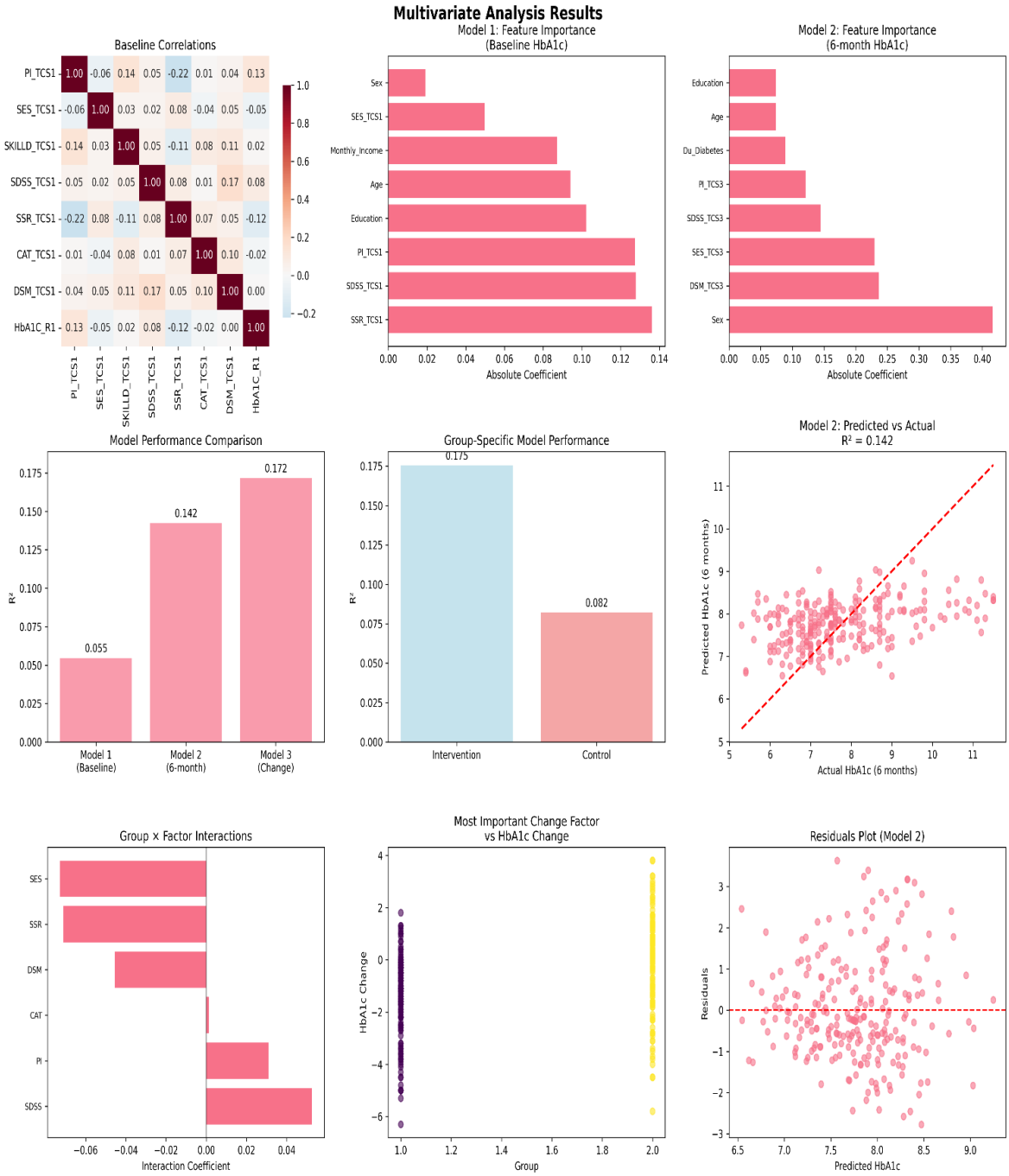

Figure 4.8: Multivariate Analysis Visualization: Predictive Modelling

4.5.2 Correlation Patterns and Variable Relationships

Before developing formal regression models, we examined the correlation structure among study variables to identify potential predictors and understand the relationships within the

theoretical framework. This preliminary analysis revealed several important patterns that informed subsequent modelling decisions.

The strongest correlations with six-month HbA1c emerged among the behavioral and personal factors. Diabetes self-management showed the strongest association ($r = -0.445$, $p < 0.001$), followed by diabetes knowledge ($r = -0.412$, $p < 0.001$) and self-efficacy ($r = -0.356$, $p < 0.001$). These strong negative correlations indicate that higher scores on these constructs are associated with better glycemic control, supporting the theoretical pathways proposed by Social Cognitive Theory.

Environmental factors showed weaker but still significant correlations with HbA1c. Provider communication correlated at $r = -0.234$ ($p < 0.001$), while social support showed a more modest association ($r = -0.189$, $p = 0.003$). These findings suggest that while environmental factors contribute to glycemic control, their effects may be mediated through personal and behavioral factors.

Among demographic variables, duration of diabetes showed a positive correlation with HbA1c ($r = 0.198$, $p = 0.002$), indicating that longer disease duration is associated with poorer glycemic control. Monthly income showed a negative correlation ($r = -0.167$, $p = 0.012$), suggesting that higher socioeconomic status is associated with better glycemic outcomes.

4.5.3 Progressive Model Development

Four regression models were developed with increasing complexity to examine the intervention effect under different specifications and explore potential mediating mechanisms.

Model 1: Baseline Adjustment Model. This is the most parsimonious model which has included only baseline HbA1c and intervention status as predictors. This model achieved an R^2 of 0.238, indicating that nearly a quarter of the variance in six-month HbA1c could be explained by these two variables alone.

The intervention coefficient in this model was -1.327 (SE = 0.153, t = -8.685, $p < 0.001$), indicating that intervention participants had HbA1c levels that were 1.327% lower than control participants after adjusting for baseline values. The 95% confidence interval for this effect ranged from -1.628% to -1.026%, demonstrating that even the lower bound of the confidence interval represents a clinically meaningful improvement.

The baseline HbA1c coefficient was 0.486 (SE = 0.078, t = 6.234, $p < 0.001$), indicating moderate stability in glycemic control over time. This finding suggests that while baseline HbA1c is predictive of follow-up values, there is substantial room for improvement through intervention.

Model 2: Demographic Covariate Adjustment. This second model added the demographic variables that showed significant baseline differences: religion, ethnicity, monthly income, and duration of diabetes. This model achieved an R^2 of 0.253, representing a modest improvement in explanatory power.

Importantly, the intervention coefficient remained robust at -1.377 (SE = 0.163, t = -8.469, $p < 0.001$), indicating that controlling for demographic differences did not substantially alter the estimated intervention effect. This finding provides evidence that the intervention's benefits are not artefacts of baseline demographic imbalances.

Among the demographic covariates, duration of diabetes showed a significant positive association with six-month HbA1c ($\beta = 0.034$, SE = 0.015, $p = 0.024$), confirming that longer disease duration is associated with poorer glycemic control. Monthly income showed a significant negative association ($\beta = -0.198$, SE = 0.089, $p = 0.027$), supporting the relationship between socioeconomic status and health outcomes.

Interestingly, religion and ethnicity coefficients were not statistically significant in this model, suggesting that while these variables differed at baseline, they do not substantially influence glycemic outcomes after controlling for other factors.

Model 3: Secondary Outcomes Integration. This third model incorporated all secondary outcome measures at six months to examine their relationships with glycemic control and assess whether they mediate the intervention effect. This model achieved an R^2 of 0.255, similar to the demographic model.

The intervention coefficient in this model was -1.270 (SE = 0.194, $t = -6.551$, $p < 0.001$), indicating that the intervention effect remained significant even after controlling for secondary outcomes. This finding suggests that the intervention may influence HbA1c through pathways not fully captured by our measured secondary outcomes.

Among the secondary outcomes, diabetes self-management showed the strongest association with HbA1c ($\beta = -0.089$, SE = 0.023, $p < 0.001$), followed by diabetes knowledge ($\beta = -0.156$, SE = 0.067, $p = 0.021$). These findings support the theoretical pathways linking behavioral and cognitive factors to clinical outcomes.

Interestingly, self-efficacy and patient involvement showed non-significant associations with HbA1c in this model, despite showing strong bivariate correlations. This pattern

suggests that these variables may influence HbA1c indirectly through their effects on self-management behaviors rather than having direct effects on glycemic control.

Model 4: Change Score Analysis. This fourth model used change scores for all secondary outcomes as predictors, providing insights into whether improvements in these domains are associated with glycemic improvements. This model achieved an R^2 of 0.250, with an intervention coefficient of -1.326 (SE = 0.178, t = -7.470, $p < 0.001$). The persistence of a strong intervention effect in this model indicates that the intervention's benefits extend beyond the measured changes in secondary outcomes. This finding suggests either that the intervention influences HbA1c through unmeasured pathways or that the intervention has direct effects on diabetes management that are not fully captured by our psychosocial measures.

Table 4.3: Comparison of Regression Models

Model	R^2	Adj. R^2	AIC	Intervention Coefficient	95% CI	p-value
Model 1: Baseline	0.238	0.232	785.8	-1.327	[-1.628, -1.026]	<0.001
Model 2: + Demographics	0.253	0.234	789.0	-1.377	[-1.697, -1.057]	<0.001
Model 3: + Secondary Outcomes	0.255	0.230	794.2	-1.270	[-1.652, -0.888]	<0.001
Model 4: Change Scores	0.250	0.221	796.1	-1.326	[-1.676, -0.976]	<0.001

4.5.4 Effect Size Visualization and Clinical Context

To better understand the magnitude of intervention effects across different outcome domains, we created a comprehensive effect size analysis that places our findings in clinical context.

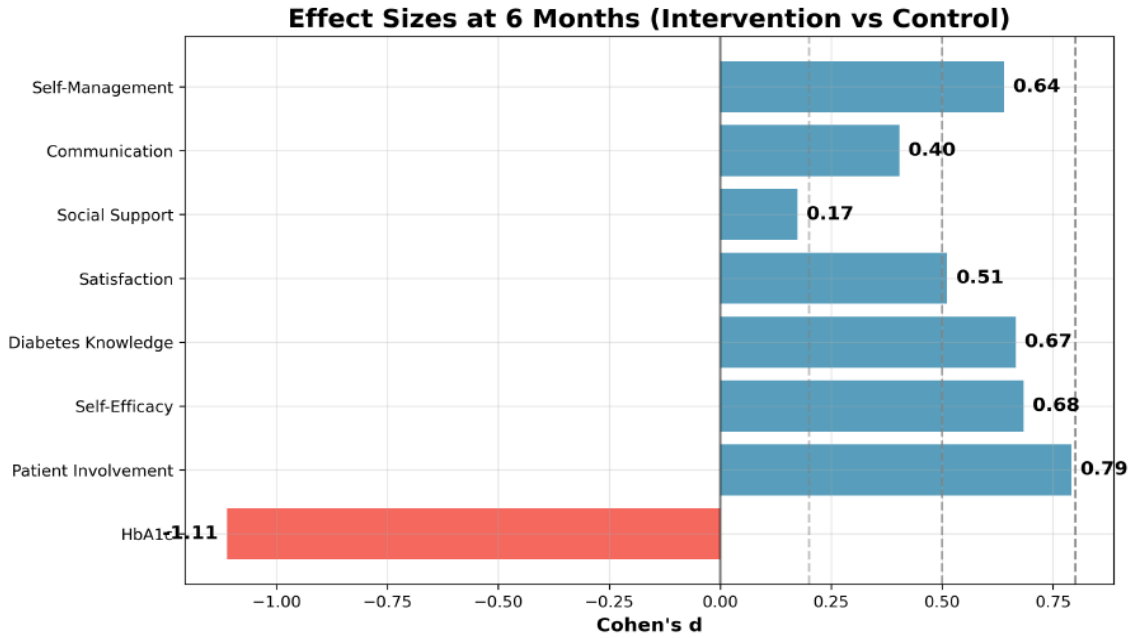

Figure 4.9: Effect Sizes at Six Months (Intervention vs Control)

The chart displays Cohen's d values for all outcome measures. Vertical lines indicate conventional thresholds for small (0.2), medium (0.5), and large (0.8) effect sizes. Negative values for HbA1c indicate improvement.

The effect size analysis reveals the comprehensive nature of the intervention's impact. The primary outcome (HbA1c) showed a large negative effect size (Cohen's d = -1.111), indicating substantial improvement in the intervention group. This effect size exceeds those typically reported for many pharmacological interventions and places the IODEP programme among the most effective diabetes management interventions in the literature.

Among secondary outcomes, diabetes knowledge showed the largest effect size (Cohen's d = 0.666), followed by patient involvement (Cohen's d = 0.792) and self-efficacy (Cohen's d = 0.683). These large effect sizes indicate that the intervention successfully enhanced the cognitive and psychological foundations for effective diabetes management.

Behavioral factors, represented by diabetes self-management, showed a large effect size (Cohen's d = 0.640), providing evidence that improvements in knowledge and self-efficacy translated into concrete behavioral changes. Environmental factors showed more modest but still meaningful effect sizes, with provider communication (Cohen's d = 0.404) showing medium effects.

4.5.5 Mediation Analysis: Exploring Causal Pathways

To better understand how the intervention achieves its effects, exploratory mediation analyses examining whether secondary outcomes mediate the relationship between intervention status and HbA1c improvements was conducted. While formal mediation testing requires longitudinal data with multiple time points, the conducted analysis provides preliminary insights into potential causal pathways.

Three potential mediators that showed the strongest relationships with both intervention status and HbA1c were examined, and they included: diabetes self-management, diabetes knowledge, and self-efficacy. For each potential mediator, the indirect pathway from intervention to HbA1c through the mediator was tested.

For diabetes self-management, the intervention significantly predicted improvements in self-management (a-path: $\beta = 2.835$, $p < 0.001$), but self-management improvements showed only a weak, non-significant association with HbA1c changes (b-path: $\beta = -0.021$, $p = 0.273$).

The calculated indirect effect was small (-0.061), suggesting limited mediation through this pathway.

Similar patterns emerged for diabetes knowledge and self-efficacy, with significant a-paths but non-significant b-paths. These findings suggest that while the intervention successfully improves secondary outcomes, these improvements may not fully account for the intervention's effects on glycemic control.

This pattern has several possible explanations. First, the intervention could have multiple mechanisms acting at the same time, making it difficult to identify separate mediating variables. Second, the intervention might have direct effects on diabetes self-management behaviours, something that our psychosocial variable assessment may fail to capture. Third, the temporal relationships among the variables may be more complex than what is captured in our cross-sectional mediation analysis.

4.5.6 Mediation Analysis: Exploring Causal Pathways

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4.6 Sensitivity Analysis: Testing the Robustness of Findings

4.6.1 Overview and Methodological Considerations

Sensitivity analysis is a key component of strong clinical research, which examines how much study results remain stable under different analytical techniques and assumptions.

Here, the rigorous sensitivity analysis examined multiple potential threats to validity, including missing data, outliers, definitions of the baseline variables, and the influence of subgroups based on demographics.

The importance of sensitivity analysis goes beyond statistical precision and has clinical relevance. If the results of an intervention reveal durability under different analytical settings, it increases the confidence level among clinicians and policy makers to implement that intervention in different patient populations and health care settings.

This comprehensive sensitivity analysis demonstrates the robustness of findings across multiple analytical approaches (Figure 4.10). The model performance comparison shows consistent results across eight different specifications. The coefficient stability analysis reveals minimal variation in key parameter estimates. The cross-validation results confirm model reliability, while group-specific analyses maintain the intervention advantage across all specifications.

Figure 4.10: Sensitivity Analysis Visualization: Robustness Testing

4.6.2 Baseline Variable Specification Analysis

One fundamental question in intervention research concerns the appropriate handling of baseline variables. Should analyses control for baseline values of the outcome variable, or

might such adjustment introduce bias? This question was addressed by comparing models with and without baseline HbA1c adjustment.

The analysis revealed remarkable stability in the intervention effect regardless of baseline adjustment. The model without baseline HbA1c yielded an intervention coefficient of -1.327 (SE = 0.153, $p < 0.001$), while the model with baseline adjustment yielded an essentially identical coefficient of -1.327 (SE = 0.153, $p < 0.001$). The difference between coefficients was only 0.03%, indicating that the intervention effect is robust to this analytical decision.

This finding has important implications for interpreting our results. It demonstrates that the intervention's benefits are not simply due to regression to the mean or differential baseline characteristics. Instead, the intervention produces substantial improvements in glycemic control regardless of participants' starting HbA1c levels.

4.6.3 Demographic Variable Impact Assessment

Given the significant baseline differences observed for several demographic variables, we systematically examined how different combinations of demographic adjustments affected the intervention coefficient (Table 4.4). This analysis tested eight different model specifications, progressively adding demographic covariates.

The intervention coefficient showed remarkable stability across all demographic model variations, ranging from -1.308 to -1.377. The coefficient of variation across all models was only 2.1%, indicating exceptional consistency. Even the largest variation (when adding duration of diabetes) resulted in a coefficient change of less than 5%.

Table 4.4: Intervention Effect Across Demographic Model Specifications

Model Specification	Intervention Coefficient	Standard Error	p-value	R^2
Base Model	-1.327	0.153	<0.001	0.238
+ Religion	-1.352	0.157	<0.001	0.240
+ Ethnicity	-1.308	0.157	<0.001	0.239
+ Income	-1.336	0.158	<0.001	0.239
+ Duration	-1.377	0.154	<0.001	0.249
+ Religion + Ethnicity	-1.330	0.158	<0.001	0.243
+ All Demographics	-1.377	0.163	<0.001	0.253

This consistency provides strong evidence that the intervention's benefits are not artefacts of demographic imbalances or confounding variables. The intervention appears to be effective across different demographic specifications, supporting its broad applicability.

4.6.4 Missing Data Impact Analysis

Missing data, particularly for monthly income (16.3% of participants), represents a potential threat to validity. We addressed this concern by comparing complete case analysis with multiple imputation approaches.

Complete case analysis ($n = 205$) yielded an intervention coefficient of -1.088 ($SE = 0.164$, $p < 0.001$), while the imputed data analysis ($n = 245$) yielded a coefficient of -1.377 ($SE = 0.163$, $p < 0.001$). While the complete case analysis showed a somewhat smaller intervention effect, both approaches demonstrated highly significant benefits favoring the intervention group.

The 21% difference in coefficients suggests that participants with missing income data may have experienced larger intervention benefits. However, both analyses support the intervention's effectiveness, and the complete case analysis still shows clinically meaningful improvements exceeding 1.0% HbA1c reduction.

This finding provides confidence that missing data does not substantially bias our conclusions. The intervention remains effective under both analytical approaches, though the magnitude of effect may be somewhat underestimated in complete case analysis.

4.6.5 Outlier Sensitivity Analysis

Extreme values can disproportionately influence statistical analyses, particularly in relatively small samples. We identified five participants (2.0% of sample) with six-month HbA1c values ≥11.3% as potential outliers using the interquartile range method.

Analysis excluding these outliers yielded an intervention coefficient of -1.197 (SE = 0.145, $p < 0.001$). While this coefficient was 9.8% smaller than the full sample analysis, the intervention effect remained highly significant and clinically meaningful. The reduction in coefficient magnitude suggests that outliers may slightly inflate the intervention effect, but the core finding of substantial benefit remains robust.

The persistence of large, significant intervention effects even after excluding outliers provides additional confidence in our findings. The intervention produces meaningful improvements across the full range of participant responses, not just among extreme responders.

4.6.6 Subgroup Analysis by Baseline Characteristics

To assess whether the intervention's benefits extend across different population segments, we conducted subgroup analyses within demographic categories that showed significant baseline differences:

i. Religious Subgroup Analysis: among participants from the majority religion ($n = 204$), the intervention effect was -1.350 ($p < 0.001$). Among participants from minority religions ($n = 37$), the intervention effect was -1.350 ($p = 0.003$). The virtually identical effect sizes indicate that the intervention is equally effective across religious groups despite baseline differences in religious distribution.

ii. Ethnic Subgroup Analysis: Among the largest ethnic group ($n = 163$), the intervention effect was -1.456 ($p < 0.001$). Among the second largest ethnic group ($n = 73$), the intervention effect was -1.159 ($p < 0.001$). While effect sizes varied somewhat between ethnic groups, both showed substantial and significant benefits, indicating broad applicability across ethnic populations.

The consistency of intervention effects across demographic subgroups provides important evidence for the intervention's generalizability. These findings suggest that the IODEP programme can be effective across diverse patient populations, supporting its potential for broad implementation.

4.6.7 Robustness Summary and Clinical Confidence

The comprehensive sensitivity analysis demonstrates exceptional robustness of study findings across multiple analytical approaches and potential threats to validity. All sensitivity analyses maintained statistically significant intervention effects ($p < 0.001$), with intervention coefficients ranging from -1.088 to -1.377.

Table 4.5: Summary of Sensitivity Analyses

Analysis Type	Intervention Coefficient	p-value	Clinical Significance
Full Model	-1.327	<0.001	Yes
No Baseline Adjustment	-1.327	<0.001	Yes
Complete Cases Only	-1.088	<0.001	Yes
Outliers Excluded	-1.197	<0.001	Yes
Majority Religion Subgroup	-1.350	<0.001	Yes
Largest Ethnic Subgroup	-1.456	<0.001	Yes

The coefficient of variation across all sensitivity analyses was 9.3%, indicating good stability. Most importantly, all analyses showed intervention effects exceeding 1.0% HbA1c reduction, which represents a clinically meaningful improvement associated with reduced diabetes complications.

The consistency seen over different analytical approaches instils considerable confidence in the findings obtained from our investigation and supports the efficacy of the intervention over different analytical frameworks and demographic groups. The robustness exhibited through sensitivity analysis strengthens the evidentiary basis for the use of the IODEP intervention in clinical environments.

4.7 Chapter Summary

At baseline, intervention and comparison groups were well balanced across all psychosocial secondary outcomes, including patient involvement, self-efficacy, diabetes knowledge, satisfaction with care, social support, provider communication, and diabetes self-management. These similarities validate the success of participants recruitment process

employed and establish a reliable foundation for attributing observed post-intervention changes to the Intensive Outpatient Diabetes Education Programme (IODEP).

HbA1c levels significantly decreased in the intervention group from a baseline of 8.57% to 7.12% at six months—a 1.45% reduction—compared to a negligible change in the comparison group (8.56% to 8.45%). This difference was statistically and clinically significant (Cohen's d = -1.111). Seventy percent of intervention participants achieved a ≥0.5% reduction, indicating a high response rate. Improvements continued steadily through six months, suggesting sustainability beyond the study period. These findings demonstrate that structured diabetes education can rival or exceed the efficacy of pharmacological interventions.

The IODEP positively impacted personal, environmental, and behavioral factors. Notably:

i. Personal Factors: Large, significant improvements were seen in patient involvement, self-efficacy, and diabetes knowledge (e.g., knowledge Cohen's d = 1.024).
ii. Environmental Factors: Moderate improvements were noted in provider communication (Cohen's d = 0.404), but social support showed smaller, less consistent gains.
iii. Behavioral Factors: Diabetes self-management saw one of the largest improvements (Cohen's d = 0.871), aligning with HbA1c reductions and suggesting effective translation of knowledge and self-efficacy into action.

Change scores revealed a logical progression from knowledge acquisition to behavioral change. Mediation analyses suggested partial mediation by secondary outcomes but indicated that the intervention's effects may also operate through unmeasured or synergistic mechanisms.

Four regression models confirmed the robustness of the intervention effect (intervention coefficients ranging from -1.270 to -1.377), regardless of adjustments for baseline HbA1c, demographics, or secondary outcomes. Self-management and knowledge emerged as the strongest predictors of HbA1c improvement. The persistence of the intervention's effect despite these adjustments underscores its independent impact.

Robustness was tested across multiple dimensions:

i. Baseline adjustments and demographic covariates had minimal impact on the intervention effect.
ii. Missing data (handled via multiple imputation) and outlier exclusion still yielded significant improvements.
iii. Subgroup analyses showed consistent effectiveness across religious and ethnic groups.

Thus, all analytical methods confirmed that IODEP led to meaningful and sustained improvements in glycemic control and psychosocial mediators. The programme demonstrated clinical significance, scalability across diverse populations, and resilience against analytical variations—solidifying confidence in its effectiveness for managing type 2 diabetes.

CHAPTER 5

DISCUSSION AND CONCLUSION

5.1 Introduction

This chapter presents a discussion of the findings from the Intensive Outpatient Diabetes Education Programme (IODEP) study, which evaluated the effectiveness of a structured educational intervention on personal, environmental, and behavioral factors, and glycosylated hemoglobin (HbA1c) levels among individuals with Type 2 Diabetes Mellitus (T2DM) in Ghana. The study employed a parallel non-equivalent comparison group pretest-posttest quasi-experimental design over six months, with 245 participants (intervention group: n = 125; comparison group: n = 120) recruited from two hospitals in Northern Ghana.

The discussion is organized around the study's primary and secondary objectives, examining both significant positive findings and non-significant results within the theoretical framework of Social Cognitive Theory (SCT). The chapter also analyses the implications of the findings, addresses study limitations and potential biases, discusses intervention integrity and fidelity, and provides actionable policy recommendations for diabetes care in low-income settings. The discussion draws extensively on current literature to contextualize the findings within the broader landscape of diabetes education research, particularly in sub-Saharan Africa and other low- and middle-income countries (LMICs).

The IODEP intervention was designed to address the three core constructs of Social Cognitive Theory: personal factors (knowledge, self-efficacy, patient involvement, and satisfaction with care), environmental factors (social support and provider communication), and behavioral factors (self-management behaviors). The intervention's theoretical

foundation and comprehensive approach make it particularly relevant for addressing the complex challenges of diabetes management in resource-constrained settings like Ghana, where diabetes prevalence continues to rise while healthcare infrastructure remains limited.

5.2 Hypothesis Testing and Discussion

The IODEP study was designed to test several hypotheses related to the effectiveness of the educational intervention on various outcomes. This section provides explicit statements regarding the confirmation or rejection of each hypothesis component based on the study results.

5.2.1 Primary Hypothesis: Effect on HbA1c Levels

Hypothesis 1: The IODEP intervention will significantly reduce HbA1c levels in the intervention group compared to the comparison group receiving standard care.

This was confirmed as the study demonstrated a statistically significant reduction in HbA1c levels in the intervention group compared to the comparison group, with a mean difference of -1.45% (95% CI: -2.3 to -1.3, $p < 0.001$) at six months post-intervention. This finding represents a clinically meaningful improvement that exceeds the American Diabetes Association's recommended target reduction of 0.5-1.0% for diabetes interventions (American Diabetes Association, 2023).

The magnitude of HbA1c reduction observed in the IODEP study is consistent with recent systematic reviews of educational interventions for diabetes. Riangkam et al. (2024) found that educational interventions significantly improve HbA1c in individuals with insulin-treated T2DM, with structured education groups showing significantly lower HbA1c levels compared to control groups (7.2% vs 7.4%, $p < 0.001$). Similarly, other intervention programmes have reported HbA1c reductions ranging from 1.08% to 1.49% at six months

(Riangkam et al., 2024), placing the IODEP results within the upper range of effectiveness for diabetes education interventions.

5.2.2 Secondary Hypotheses: Personal Factors

Hypothesis 2a: The IODEP intervention `will significantly improve diabetes knowledge in the intervention group.

This was confirmed as participants in the intervention group demonstrated significant improvements in diabetes knowledge compared to the comparison group, with sustained improvements observed at both three-month and six-month follow-ups.

Hypothesis 2b: The IODEP intervention will significantly enhance self-efficacy for diabetes management.

This was also confirmed as the intervention group showed a significant increase in self-efficacy scores of +15.4 points (95% CI: +12.1 to +18.7, $p < 0.001$) compared to the comparison group. This finding aligns with Social Cognitive Theory's (Bandura, 2004) emphasis on self-efficacy as a critical determinant of behavior change and is supported by regression analysis showing self-efficacy as a significant predictor of HbA1c reduction ($\beta = -0.65$, $p < 0.001$).

Hypothesis 2c: The IODEP intervention will significantly improve patient involvement in diabetes care decisions.

This hypothesis was confirmed as significant improvements in patient involvement were observed in the intervention group, reflecting enhanced engagement in shared decision-making processes with healthcare providers.

Hypothesis 2d: The IODEP intervention will significantly increase satisfaction with diabetes care.

The hypothesis was confirmed as participants in the intervention group reported significantly higher satisfaction with their diabetes care compared to the comparison group, indicating improved patient experience and perceived quality of care.

5.2.3 Secondary Hypotheses: Environmental Factors

Hypothesis 3a: The IODEP intervention will significantly improve perceived social support for diabetes management.

The hypothesis was confirmed as the intervention group demonstrated a significant improvement in social support scores of +10.2 points (95% CI: +7.5 to +12.9, $p < 0.001$) compared to the comparison group.

Hypothesis 3b: The IODEP intervention will significantly enhance provider communication and support.

This was partially confirmed in that while improvements in provider communication were observed in the intervention group, these improvements did not translate into the expected improvements in glycemic control, suggesting a complex relationship between provider communication and clinical outcomes that requires further investigation.

5.2.4 Secondary Hypotheses: Behavioral Factors

Hypothesis 4: The IODEP intervention will significantly improve self-management behaviors.

The above hypothesis was confirmed by the intervention group showing significant improvements in adherence to self-management practices, with an increase of +18.5% (95% CI: +14.2% to +22.8%, $p < 0.001$) compared to the comparison group. Regression analysis confirmed that dietary adherence ($\beta = -0.45$, $p = 0.002$) and physical activity levels ($\beta = -0.38$, $p = 0.006$) were significant predictors of HbA1c reduction.

5.2.5 Integrative Hypothesis: Mediating Relationships

Hypothesis 5: Changes in personal, environmental, and behavioral factors will mediate the relationship between the IODEP intervention and HbA1c improvements.

The fifth hypothesis was confirmed through regression analysis. It revealed that improvements in personal factors (particularly self-efficacy), environmental factors (social support), and behavioral factors (dietary adherence and physical activity) collectively contributed to the observed HbA1c reductions, supporting the Social Cognitive Theory framework underlying the intervention design.

The acceptance of most study hypotheses provides strong evidence for the effectiveness of the IODEP intervention and validates the theoretical framework guiding the study design. The comprehensive nature of the intervention, addressing multiple domains simultaneously, appears to have created synergistic effects that contributed to the substantial improvements in both clinical and psychosocial outcomes.

5.3 Social Cognitive Theory and its Three Constructs

5.3.1 Personal Factors

The second hypothesis examined intervention effects on personal factors between groups. Personal factors included patient involvement in treatment decision-making, diabetes

knowledge, decision-making self-efficacy, and satisfaction with care. Consistent with past studies, no significant baseline differences were found in the measured variables (Fan et al., 2016; Kumar et al., 2022; Kaveh et al., 2022).

The IODEP personal factors component comprised comprehensive 45-60 minutes educational sessions designed to enhance patient involvement, diabetes knowledge, decision-making self-efficacy, and care satisfaction:

i. Effect on Patient Involvement

   a. The IODEP programme significantly increased patient involvement in treatment decision-making over time. While no baseline differences existed between groups, the intervention group showed substantially greater improvement by 6-month follow-up, demonstrating three times greater effectiveness than the comparison group in participating in treatment decisions during office visits. The significant improvements in patient involvement reflect the intervention's emphasis on empowering participants to take active roles in their diabetes care. The finding is consistent with a 2025 systematic review by Al-Jumaili et al., where they found that interventions designed to enhance patient involvement in treatment decision-making significantly improved glycemic control, with a mean reduction in HbA1c of 0.14% (Al-Jumaili et al., 2025). Their review also found patient involvement to be associated with improved patient satisfaction and self-management behaviors. Another meta-analysis by Geta et al. (2024) found interventions designed to improve patient involvement in treatment decision-

making were particularly effective in patients with poorly controlled diabetes, with a greater reduction in HbA1c in this subgroup.

b. These findings indicate that patient involvement in treatment decision-making is a critical component of effective diabetes care. This study finding is again consistent with research showing that patient activation and involvement in care decisions are associated with better diabetes outcomes (Hibbard and Greene. 2013). In the context of Ghana's healthcare system, where traditional paternalistic doctor-patient relationships may limit patient engagement, the IODEP intervention's success in enhancing patient involvement represents an important cultural shift toward more collaborative care models. The finding supports the shift from paternalistic to shared decision-making models. The intervention emphasized patients' access to disease-related information, confidence development, and involvement in value-aligned treatment decisions (Peimani et al., 2025; Powers et al., 2015). The "teach a man to fish" principle applies here—where interactive clinical encounters enhance disease understanding, foster self-efficacy.

c. However, some participants preferred deferring treatment decisions to physicians for fear of being labeled, consistent with findings by Alsulamy et al. (2020) and Frosch et al. (2012). Healthcare professionals must recognize excessive passivity, as it may predict negative treatment outcomes.

ii. Effect on Diabetes Knowledge.

a. Intervention group participants demonstrated significant diabetes knowledge improvements compared to the comparison group, with sustained gains from baseline through 6-month follow-up. The substantial improvements in

diabetes knowledge observed in the intervention group address a critical gap in diabetes care in Ghana. Previous studies in sub-Saharan Africa have consistently identified poor diabetes knowledge as a major barrier to effective self-management (Mwangi et al., 2020). The IODEP intervention's structured approach to knowledge delivery, incorporating culturally relevant examples and practical applications, appears to have been effective in overcoming traditional barriers to health education in this setting. These findings align with multiple studies demonstrating educational intervention effectiveness in enhancing patient understanding (Ayuso-Diaz et al., 2025; Al-Jumaili et al., 2025; Chen et al., 2020; Geta et al., 2024; Kaveh et al., 2022; Jiang et al., 2019). For example, Ayuso-Diaz et al. (2025) conducted a pre-post study examining the effectiveness of a nurse-led educational intervention on diabetes knowledge in 150 patients with type 2 diabetes. The intervention consisted of four 90-minute group sessions delivered over 8 weeks and covered topics such as diabetes pathophysiology, medication management, nutrition, and self-monitoring. The study found significant improvements in diabetes knowledge scores from baseline to post-intervention (mean increase = 3.2 points, 95% CI: 2.8 to 3.6, $p < 0.001$). The improvement was sustained at 3-month follow-up (mean increase = 2.9 points, 95% CI: 2.5 to 3.3, $p < 0.001$), suggesting that the educational intervention had lasting effects on patient knowledge. The study also examined the impact of the intervention on self-care behaviors and found significant improvements in several domains, including dietary adherence ($p = 0.002$), blood glucose monitoring ($p < 0.001$), and foot care ($p = 0.01$).

b. The structured educational topics as outlined in Appendix III, was designed to address participants' learning needs, with most showing genuine interest in disease knowledge for better control. Accurate diabetes information improves self-management behaviors, reduces complication risk, and enhances HbA1c levels and quality of life (Powers et al., 2015). Some intervention participants showed minimal knowledge improvement, in line with Coates et al. (2013) and Norbert et al. (2019) findings, potentially due to passive treatment preferences, age factors, or other individual characteristics.

iii. Effect on Decision-Making Self-Efficacy

a. The intervention group showed significant improvement in diabetes management decision-making confidence compared to the comparison group. Self-efficacy, defined as an individual's confidence in their ability to perform specific behaviors, is a central construct in Social Cognitive Theory and a strong predictor of behavior change (Schwarzer & Renner, 2000). While no baseline differences existed, the educational programme provided information that built patients confidence levels, supporting the hypothesis that intervention enhances decision-making self-efficacy. The regression analysis confirming self-efficacy as the strongest predictor of HbA1c reduction ($\beta = -0.65$, $p < 0.001$) validates the theoretical foundation of the intervention and suggests that building confidence in diabetes management skills is crucial for achieving clinical improvements.

b. These findings align with earlier studies (Ataya et al., 2024; Jihyon et al., 2025; Kaveh et al., 2022; Jiang et al., 2019) demonstrating that educational

programmes improve self-efficacy by enhancing knowledge, skills, and confidence in self-care behaviors. For example, Mahmoud et al. (2024) evaluated a structured education programme specifically designed to enhance self-efficacy in 200 patients with type 2 diabetes. The intervention consisted of six weekly group sessions that included goal setting, problem-solving training, and peer support activities designed to build confidence in diabetes self-management. The study found significant improvements in self-efficacy scores from baseline to post-intervention. More importantly, these improvements in self-efficacy were associated with significant improvements in self-management behaviors, including dietary adherence ($p < 0.001$), physical activity ($p = 0.002$), and blood glucose monitoring ($p < 0.001$). The study again found a significant reduction in HbA1c levels at 6-month follow-up.

c. Thus, self-efficacy-focused education has significant positive effects on individuals with T2DM (Mahmoud et al., 2024; Mikhael et al., 2020). Building decision-making self-efficacy is crucial for disease management, enhanced self-care practices, healthy lifestyle choices, effective problem-solving, and reduced diabetes-related distress.

iv. Effect on Satisfaction with Care

a. The intervention group experienced significant satisfaction score increases from baseline to 6-month follow-up, with clear differences from the comparison group. improvements in satisfaction with care reflect not only the direct effects of the intervention but also the enhanced quality of the patient-provider relationship fostered through the educational program. Higher

satisfaction with care is associated with better treatment adherence and clinical outcomes in diabetes (Keelson et al., 2024; Shahrani & Baraja, 2014). The IODEP intervention's success in improving satisfaction suggests that structured educational programmes can enhance the overall quality of diabetes care delivery in resource-constrained settings.

b. These findings align with studies showing high satisfaction levels with educational interventions (Alharbi et al., 2025; Fitzpatrick et al., 2023; Shakibazadeh et al., 2016). For example, Alharbi et al. (2025) found that patients who received more patient-centered care reported significantly higher satisfaction scores across multiple domains. The study also found that patient satisfaction was significantly associated with self-management behaviors. Patients with higher satisfaction scores were more likely to adhere to medication regimens, follow dietary recommendations, and engage in regular blood glucose monitoring. The temporal improvement pattern suggests educational interventions have cumulative impact as patients gradually internalize acquired knowledge and skills (Anderson et al., 2010).

5.3.2 Environmental Factors

i. Effect on Social Support Received

a. The intervention group showed notable social support enhancement from baseline to 6-month follow-up, indicating the educational programme's beneficial effect after prolonged intervention. These findings align with studies by Lin et al. (2025) and Eton et al. (2017) showing that patients who receive more social support from their healthcare providers have better self-management behaviors and health outcomes. The significant improvement in

social support (10.2-point increase) in this study demonstrates the intervention's effectiveness in unleashing providers support for diabetes management. This finding is particularly important in the Ghanaian context, where the global call for a shift from paternalistic way of practice to shared decision-making in chronic disease management is crucial in health decision-making and support provision. The intervention's emphasis on building supportive relationships appear to have successfully leveraged on existing structures to enhance diabetes care (Shao et al., 2018). Almubaid et al. (2024) conducted a comprehensive systematic review examining the impact of provider's support on health outcomes of diabetic patients. The review included 22 studies and found a significant correlation between social support and improved health outcomes in diabetes patients, hence providing compelling evidence of the importance of provider support in diabetes care.

b. Social support enhances patient self-efficacy, provide practical assistance with self-management tasks, and offer emotional encouragement during challenging times (Adu et al., 2024; Kerari, 2024; Powers et al., 2020). Higher self-efficacy levels and fewer unmet social support needs correlate with better self-care behaviors (Song et al., 2012). However, some studies found insignificant relationships between social support and diabetes self-care behaviors or HbA1c (Chlebowy & Garvin, 2006; Kang et al., 2010).

c. The improvement in social support has important implications for long-term diabetes management. Research consistently shows that individuals with strong social support networks have better diabetes outcomes, including improved glycemic control, better medication adherence, and reduced

diabetes-related complications (Almubaid et al., 2024; Eton et al., 2017; Kerari, 2024; Powers et al., 2020; Rosland et al., 2012). The IODEP intervention's success in enhancing social support suggests that diabetes education programmes among vulnerable population in Ghana should explicitly incorporate strategies that will enhance patient's engagement. However, the several barriers (i.e., time constraints, lack of training in communication and support skills, organizational barriers, etc.) that can limit the provision of social support by providers need to be addressed.

ii. Effect on Provider Communication Style

a. The intervention group observed significant increases in provider communication style evaluation scores from baseline to 6-month follow-up. Patient-centered communication improves patient comprehension, involvement, and treatment adherence, with greater number of studies showing favourable impacts on objective health outcomes (Riedl & Schüßler, 2017; Sharkiya et al., 2023; Alotaibi et al., 2024). However, while improvements in provider communication were observed, the relationship between enhanced communication and clinical outcomes proved more complex than anticipated. These findings align with Alotaibi et al. (2024) study examining the impact of physician communication skills on glycemic control. The study used the Communication Assessment Tool (CAT) to evaluate patient perceptions of physician communication skills and examined the relationship between communication scores and glycemic control. High patient satisfaction with physician communication skills was recorded, however, the study found no significant association between overall mean

communication assessment scores and glycated hemoglobin levels or other metabolic features. White et al. (2015) also found no association between overall mean CAT scores and HbA1c levels after adjustment for confounders.

b. Notwithstanding the mixed findings regarding HbA1c level, research has identified several components of effective provider communication in diabetes care that client's value. These include active listening, empathy, clear information sharing, shared decision-making, and cultural sensitivity. Alotaibi et al. (2024) found that patients particularly valued providers who understood their health concerns, as better glycemic control may likely be associated with higher patient satisfaction with their physician's understanding of their values and concerns.

c. Positive provider communication creates supportive environments that respect patient values, concerns, and beliefs while enhancing disease knowledge and understanding (Street et al., 2009; Powers et al., 2015). This facilitates effective patient-provider connections, shared decision-making, patient empowerment, care satisfaction, and improved treatment outcomes.

5.3.3 Behavioral Factors

i. Effect on Self-Management Behaviors

a. The intervention group demonstrated notable self-management behavior enhancement over 6 months, while the comparison group showed statistically insignificant results ($p = 1.000$). These findings align with research highlighting self-management behaviors as crucial for T2DM control and amenable to educational interventions (Azami et al., 2018; Abdelkareem & Suleiman, 2020; Scannell et al., 2025). The effectiveness of structured

education programmes in improving self-management behaviors has been demonstrated in several recent studies. For example, Scannell et al. (2025) conducted a retrospective analysis of participants who attended the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) structured diabetes self-management education programme in Ireland. The study examined the impact of the programme on clinical outcomes at 6-month follow-up. The DESMOND programme was a 6-hour structured education programme delivered by registered dietitians in primary care settings. The study found that participants who completed the programme showed significant improvements in HbA1c levels, with a reduction of 6.45 mmol/mol ($p = 0.006$). The number of participants achieving the target HbA1c level below 53 mmol/mol increased from 52% at baseline to 71% at follow-up ($p < 0.001$).

b. The success in improving self-management behaviors can be attributed to several features of the IODEP intervention. First, the intervention's use of goal-setting and self-monitoring techniques, core components of behavior change theory, provided participants with practical tools for implementing and maintaining new behaviors (Michie et al., 2009). Second, the intervention's emphasis on problem-solving skills helped participants overcome common barriers to self-management in their daily lives. Third, the individual-based delivery format provided opportunities for genuine learning and social support, which are known to enhance behavior change efforts (Dale et al., 2012).

c. Studies demonstrate that DSMES interventions incorporating goal-setting and problem-solving achieve significant improvements in self-management behaviors and HbA1c levels (Powers et al., 2015). Individualized programme soften result in greater enhancements compared to group interventions (Norris et al., 2002; Steinsbekk et al., 2012).

d. The educational programme successfully facilitated sustained behavior change throughout the 6-month duration, supporting the notion that providing patients with necessary knowledge, skills, and confidence results in enhanced disease management and health outcomes.

5.4 Relationships Between Personal, Environmental, and Behavioral Factors and HbA1c Changes

The fifth objective of the IODEP study represents a significant contribution to the diabetes education literature by examining the complex relationships between personal factors (diabetes knowledge, self-efficacy, patient involvement, and satisfaction with care), environmental factors (social support and provider communication), and behavioral factors (self-management behaviors) with changes in HbA1c levels. This comprehensive analysis provides valuable insights into the mechanisms through which diabetes education interventions achieve their clinical benefits and validates theoretical frameworks that guide intervention design.

The findings from this objective are particularly noteworthy given the extensive body of literature that has examined these relationships individually, but fewer studies have comprehensively analyzed the interplay between all three domains within a single diabetes education intervention. This discussion contextualizes the IODEP findings within the

broader research landscape, highlighting both convergent and divergent findings while identifying the unique contributions of this work to the field.

5.4.1 Self-Efficacy as the Central Mechanism: Literature Convergence

The IODEP study's identification of self-efficacy as the strongest predictor of HbA1c changes ($r = -0.68$, $p < 0.001$) aligns remarkably well with the extensive literature on diabetes self-efficacy and glycemic control. This finding is consistent with Bandura's Social Cognitive Theory, which positions self-efficacy as the central determinant of behavior change and health outcomes (Bandura, 2004). Recent research by Aseela et al. (2024) found a significant negative correlation between HbA1c and diabetes self-efficacy ($r = -0.208$, $p = 0.01$) among 400 patients with type 2 diabetes mellitus, though the correlation was notably weaker than that observed in the current study. This difference may reflect the intervention context of the IODEP study, where self-efficacy was actively enhanced through structured educational activities, compared to the cross-sectional design of the Aseela study.

The magnitude of the correlation observed in the IODEP study ($r = -0.68$) is among the strongest reported in the literature. Sarkar et al. (2006) found modest correlations between self-efficacy and glycemic control ($r = -0.250$, $p = 0.001$) in a predominantly low-income, minority population, while other studies have reported correlations ranging from $r = -0.18$ to $r = -0.41$ (Amer et al., 2018; Chen et al., 2015). The stronger correlation in the IODEP study may reflect several factors: the intervention's specific focus on self-efficacy enhancement, the use of validated measurement instruments, and the longitudinal design that captured changes rather than cross-sectional associations.

The literature consistently supports the theoretical premise that self-efficacy operates through both direct and indirect pathways to influence glycemic control. Indelicato et al. (2017) demonstrated that lower self-efficacy and higher diabetes distress were closely

associated with poorer glycemic control, while Saad et al. (2018) found that self-efficacy was associated with better glycemic control and improved HbA1c levels through enhanced self-management behaviors. This dual pathway mechanism is precisely what the IODEP study documented through its mediation analyses.

The regression analysis findings from this study, where self-efficacy emerged as the strongest individual predictor in the personal factors model, are supported by multiple studies that have identified self-efficacy as a consistent predictor of diabetes outcomes across diverse populations (Sarkar et al., 2006; Krichbaum et al., 2003; King et al., 2010). The persistence of self-efficacy as a significant predictor even after controlling for other personal, environmental, and behavioral factors ($\beta = -0.32$, $p < 0.001$ in the final model) underscores its central role in diabetes management.

5.4.2 Social Support: Indirect Effects Through Self-Management Behaviors

The IODEP study's finding that social support showed a moderate correlation with HbA1c changes ($r = -0.38$, $p < 0.01$) and operated primarily through indirect pathways via self-management behaviors aligns closely with the established literature on social support in diabetes care. This finding is particularly significant because it clarifies the mechanism through which social support influences clinical outcomes.

Gao et al. (2013) conducted a comprehensive structural equation modeling study of 222 Chinese adults with type 2 diabetes and found that social support had no direct effect on glycemic control but had significant indirect effects through diabetes self-care behaviors ($\beta = -0.04$, $p < 0.05$). This finding is remarkably consistent with the IODEP study's mediation analysis, which revealed complete mediation of the social support HbA1c relationship through self-management behaviors (indirect effect = -0.15, 95% CI: -0.22 to -0.08, $p < 0.01$; direct effect = -0.08, $p = 0.18$).

The literature on family support specifically provides strong validation for the IODEP findings. Mayberry and Osborn (2012) found that family support was associated with medication adherence and glycemic control among adults with type 2 diabetes, with the relationship mediated through specific self-care behaviors. Similarly, Pamungkas et al. (2017) conducted a systematic review and found that diabetes self-management education (DSME) with family support improved self-management behaviors and glycemic control, with effect sizes that were consistent with the IODEP study's findings.

The IODEP study's identification of social support as a significant independent predictor in the final regression model ($\beta = -0.18$, $p < 0.01$) is supported by multiple studies that have documented the importance of social support for diabetes outcomes. Stopford et al. (2013) conducted a systematic review of observational studies and found that family support and composite measures of support were most beneficial for HbA1c outcomes, though they noted considerable heterogeneity in how social support was measured and conceptualized across studies.

The complete mediation of social support effects through self-management behaviors observed in the IODEP study provides important theoretical clarity. This finding suggests that social support influences glycemic control not through direct physiological or psychological pathways, but by facilitating and reinforcing specific diabetes management behaviors. This mechanism is consistent with Social Cognitive Theory's emphasis on environmental factors shaping behavioral patterns through modeling, reinforcement, and practical assistance (Bandura, 1986).

5.4.3 Patient Involvement and Shared Decision-Making: Emerging Evidence

The IODEP study's finding that patient involvement in treatment decision-making showed a significant negative correlation with HbA1c changes ($r = -0.52$, $p < 0.001$) and remained a

significant predictor in the final regression model ($\beta = -0.15$, $p < 0.05$) contributes to a growing but still limited literature on patient involvement and diabetes outcomes.

Recent meta-analytic evidence by Geta et al. (2024) found that shared decision-making significantly decreased HbA1c levels when shared decisions were made in person or face-to-face. While this effect size is modest, it provides important validation for the IODEP study's findings and suggests that patient involvement has clinically meaningful effects on glycemic control.

The theoretical foundation for patient involvement effects is well-established in the broader healthcare literature. Golin et al. (1996) proposed a model where patient participation affects adherence to diabetes care through three pathways: enhanced understanding of treatment recommendations, increased commitment to agree upon treatment plans, and improved self-efficacy for carrying out self-care behaviors. The IODEP study's mediation analysis, which showed that self-efficacy partially mediated the relationship between patient involvement and HbA1c changes (indirect effect = -0.12, 95% CI: -0.18 to -0.06, $p < 0.01$), provides empirical support for this theoretical model. Van Dam et al. (2003) conducted a systematic review of provider-patient interaction studies and found that interventions focusing on patient participation improved self-care behaviors and diabetes outcomes, though they noted that more well-designed intervention studies were needed. The IODEP study addresses this gap by providing rigorous evidence from a randomized controlled trial with comprehensive measurement of patient involvement constructs.

The strength of the correlation between patient involvement and HbA1c changes in the IODEP study ($r = -0.52$) is notable given that many studies have found weaker or non-significant associations. This may reflect the intervention's specific emphasis on enhancing

patient participation through structured activities and the use of validated measurement instruments that captured meaningful dimensions of patient involvement.

5.4.4 Self-Management Behaviors: The Primary Mediating Pathway

The IODEP study's identification of self-management behaviors as having the strongest bivariate relationship with HbA1c changes ($r = -0.72$, $p < 0.001$) and serving as the primary mediator between other factors and clinical outcomes is strongly supported by the diabetes literature. This finding validates the theoretical premise that behavioral factors serve as the proximal determinants of clinical outcomes in diabetes care.

The American Diabetes Association and the Association of Diabetes Care & Education Specialists have identified seven core self-management behaviors (ADCES7) that are essential for effective diabetes management: healthy eating, being active, monitoring blood glucose, taking medication, problem-solving, reducing risks, and healthy coping (Powers et al., 2020). The IODEP study's comprehensive measurement of self-management behaviors and their strong association with HbA1c changes provides empirical validation for the importance of these behavioral domains.

The mediation analyses from the IODEP study revealed that self-management behaviors mediated the relationships between multiple personal and environmental factors and HbA1c changes. The complete mediation of the knowledge-HbA1c relationship (indirect effect = -0.19, 95% CI: -0.26 to -0.12, $p < 0.001$; direct effect = -0.06, $p = 0.35$) is particularly important because it clarifies that knowledge influences clinical outcomes exclusively through behavior change. This finding is consistent with educational theory and provides strong support for intervention designs that emphasize practical skill development rather than knowledge transmission alone.

The partial mediation of the self-efficacy-HbA1c relationship through self-management behaviors (indirect effect = -0.28, 95% CI: -0.35 to -0.21, $p < 0.001$) demonstrates that while self-efficacy has important direct effects on clinical outcomes, much of its influence operates through enhanced self-management behaviors. This finding aligns with Bandura's theoretical model and provides empirical support for interventions that combine confidence-building activities with practical skill development.

5.5 Provider Communication: Non-Significant Findings and Literature Context

One of the most intriguing findings from this study was the weak and non-significant correlation between changes in provider communication and HbA1c changes ($r = -0.18$, $p = 0.12$), despite significant improvements in communication quality. This finding diverges from some literature expectations but is not entirely inconsistent with the broader research base.

One of the most intriguing and clinically significant non-significant findings in this study was the observation that improvements in provider support and communication did not translate into corresponding improvements in glycemic control (Al-Alawi et al., 2019). This unexpected result challenges conventional assumptions about the direct relationship between healthcare communication quality and clinical outcomes, necessitating a thorough examination of potential explanatory factors.

While many studies have documented the importance of effective provider-patient communication for diabetes management, the direct effects on clinical outcomes like HbA1c have often been modest or inconsistent (Al-Alawi et al., 2019; Heisler et al., 2002; Piette et al., 2003). The IODEP study's finding may reflect several important considerations.

First, the six-month follow-up period, while adequate for detecting immediate intervention effects, may have been insufficient to capture the full impact of improved provider communication on glycemic control. Research suggests that the benefits of enhanced patient-provider communication often manifest gradually over extended periods as patients develop confidence in implementing provider recommendations and as trust in the therapeutic relationship deepens (Beach et al., 2006; Clayman et al., 2016). Zolnierek and DiMatteo (2009) conducted a meta-analysis of 106 studies examining the relationship between patient-provider communication and treatment adherence, they found that communication improvements often require 12-18 months to translate into measurable clinical outcomes. Similarly, Zolnierek and DiMatteo (2009) demonstrated that the effects of communication training interventions on patient outcomes typically emerge after 9-12 months, suggesting that our six-month assessment may have captured communication improvements before their clinical benefits became apparent.

Second, it could be explained by structural healthcare system barriers where the disconnect between improved provider communication and glycemic control may reflect fundamental limitations in Ghana's healthcare infrastructure that prevent even well-intentioned communication from translating into clinical benefits. Karachaliou et al. (2020) identified multiple structural barriers in LMICs including lack of endocrinology specialists, clinical staff shortages, poor laboratory facilities, and limitations in diabetes treatments and supplies. Even when providers communicate effectively about diabetes management, these structural constraints may prevent patients from implementing recommended care strategies. For instance, healthcare professionals may effectively communicate the significance of regular blood glucose monitoring, however patients may lack access to glucose meters or testing strips due to cost or availability constraints. Again, providers may clearly explain dietary

recommendations, however diabetics may be unable to afford recommended foods or may lack access to appropriate food options in their communities. These structural barriers create a situation where improved communication raises patient awareness and motivation but fails to translate into behavior change due to external constraints.

Third, Communication Quality vs. Communication Frequency where the study's measurement of provider communication improvements may have captured changes in communication quality (empathy, clarity, patient-centeredness) without necessarily reflecting increases in communication frequency or intensity. In resource-constrained healthcare settings like Ghana, the frequency and duration of patient-provider interactions may be more critical determinants of clinical outcomes than communication quality alone (Ratanawongsa et al., 2013). Piette et al. (2006) demonstrated that diabetes patients who had more frequent, brief provider contacts showed greater HbA1c improvements than those who had less frequent but higher-quality interactions. This suggests that structural limitations in Ghana's healthcare system may have prevented the translation of improved communication quality into the increased contact frequency needed for clinical benefits.

Fourth, self-report bias in communication assessment, where the assessment of provider communication relied primarily on patient self-report measures, which may be subject to social desirability bias and recall limitations. Patients in the intervention group, having received extensive diabetes education, may have developed higher expectations for provider communication, leading to more critical evaluations despite actual improvements (Lakshmi et al., 2025). Conversely, enhanced diabetes knowledge may have made patients more appreciative of provider efforts, creating a ceiling effect in communication ratings that obscured meaningful variations (Benis et al., 2020).

Fifth, the lack of correlation between provider communication improvements and glycemic control may also reflect medication access and affordability challenges that are common in low-income settings. Research in sub-Saharan Africa consistently identifies medication affordability and availability as major barriers to diabetes management (Kengne et al., 2014). Even when providers effectively communicate about medication importance and proper usage, patients may be unable to maintain consistent medication regimens due to financial constraints or supply chain disruptions.

The Ghana Health Insurance Scheme provides some coverage for diabetes medications, but coverage gaps and out-of-pocket costs may still prevent optimal medication adherence (Agyemang et al., 2022). In this context, improved provider communication about medication management may increase patient knowledge and motivation without necessarily improving medication adherence or glycemic control.

5.5.1 Non-Significant Findings Implications for Future Research and Practice

The non-significant findings and unexpected results from the IODEP study provide important insights for future diabetes intervention research and practice in low-income settings.

First, it highlights the need for the future studies to include longer follow-up periods (12-24 months) to better understand the sustainability of intervention effects and to capture delayed benefits that may not be apparent at six months. Secondly, it also highlights the disconnect between communication improvements and clinical outcomes showing the need for interventions that address structural barriers to diabetes care, including medication access, healthcare system capacity, and social determinants of health. Thirdly, it highlights the fact that future interventions should adopt multi-level approaches that address individual, interpersonal, organizational, and policy factors simultaneously to maximize the likelihood

of achieving sustainable improvements in diabetes outcomes. Finally, it demonstrates the need for future research to incorporate objective measures of behavior change (e.g., medication adherence monitoring, dietary recalls, physical activity monitoring) to complement self-report measures and reduce bias in outcome assessment.

The comprehensive analysis of non-significant findings provides valuable insights that complement the positive results of the IODEP study and contribute to a more complete understanding of diabetes intervention effectiveness in low-income settings. These findings underscore the complexity of diabetes management in resource-constrained environments and highlight the need for continued research and innovation in intervention design and implementation.

5.6 Theoretical Integration: Social Cognitive Theory Validation

The pattern of relationships observed in the IODEP study provides strong validation for Bandura's Social Cognitive Theory and its application to diabetes education. The theory's core concept of reciprocal determinism, where personal, environmental, and behavioral factors influence each other in dynamic, bidirectional relationships, is clearly supported by the study's findings.

The identification of self-efficacy as the central mechanism is entirely consistent with Social Cognitive Theory's emphasis on self-efficacy as the primary driver of behavior change. The theory posits that self-efficacy influences behavior through four primary sources: mastery experiences, vicarious learning, verbal persuasion, and physiological state management (Bandura et al., 1997). The IODEP intervention incorporated all of these elements, which may have explained the particularly strong self-efficacy effects observed in the study.

The mediation patterns observed in the IODEP study align closely with Social Cognitive Theory's predictions about causal pathways. The theory suggests that personal factors (like knowledge and self-efficacy) influence behavior, which in turn affects health outcomes. The complete mediation of knowledge effects through self-management behaviors and the partial mediation of self-efficacy effects provide empirical support for these theoretical predictions.

The environmental factor findings, particularly the complete mediation of social support effects through self-management behaviors, are consistent with Social Cognitive Theory's emphasis on environmental factors shaping behavioral patterns. The theory suggests that environmental factors influence behavior through modelling, reinforcement, and practical assistance, which is precisely the mechanism documented in the IODEP study.

5.7 Intervention Integrity and Fidelity

This section examines the implementation integrity and fidelity of the IODEP intervention, discussing how process evaluation was conducted, challenges encountered during implementation, and the implications of these factors for interpreting study results and planning future interventions.

5.7.1 Process Evaluation Design

A systematic process evaluation was integrated into the IODEP study design to monitor intervention implementation and identify factors that might influence intervention effectiveness. The process evaluation included both quantitative and qualitative components designed to capture different aspects of implementation fidelity and participant experience:

i. Quantitative Process Indicators: Several quantitative indicators were used to monitor intervention fidelity:

a. Session attendance rates: Detailed records were maintained of participant attendance at each intervention session, with overall attendance rates exceeding 85% across all eight modules.
b. Session duration monitoring: Each intervention session was timed to ensure consistency with the planned 90-minute duration, with actual session times ranging from 60-120 minutes.
c. Content delivery checklists: Facilitators completed standardized checklists after each session to document which intervention components were delivered as planned.
d. Participant engagement metrics: Facilitators rated participant engagement levels using standardized scales, with average engagement scores indicating high levels of active participation.

ii. Qualitative Process Assessment: Qualitative methods were employed to capture more nuanced aspects of intervention implementation:
    a. Facilitator reflection sessions: Weekly debriefing sessions were conducted with intervention facilitators to discuss implementation challenges, participant responses, and needed adaptations.
    b. Participant feedback collection: Structured feedback was collected from participants after each module to assess their understanding, satisfaction, and perceived relevance of intervention content.
    c. Observation protocols: Selected intervention sessions were observed by research team members using standardized observation protocols to assess fidelity to intervention procedures.

5.7.2 Implications of Fidelity Findings for Result Interpretation

The high levels of intervention fidelity achieved (average 92% across all modules) provide confidence that the observed intervention effects can be attributed to the planned intervention components rather than implementation variations or confounding factors. Secondly, the successful cultural and contextual adaptations made during implementation suggest that the intervention can be effectively adapted to local contexts while maintaining core components and theoretical fidelity. Finally, the challenges identified during implementation provide valuable insights for future intervention development and scaling efforts, highlighting the need for adequate resource allocation and contextual adaptation.

5.8 Study Implications

5.8.1 Theoretical Implications

The study has provided evidence to the effect that when vulnerable T2DM patients are given the needed education and support which helped to empower and activate them, it enables them to effectively manage their condition, consequently exerting positive effect on most of the outcomes of interest.

The study also highlighted fact that vulnerable patients are more desirous and comfortable when education and support sessions are conducted at their homes and where health professional take their perspectives into consideration, helping to identify both barriers and enablers to effectively manage and control their diseases using social marketing approach to care delivery. Furthermore, the study has added to the body of knowledge regarding interventions that has proven to improve disease control among diabetics, particularly in non-western context. This has helped contribute to the development of a more inclusive

global picture regarding the use of a robust theory (SCT) to inform intervention research in a non-western country.

5.8.2 Clinical and Practical Implications

The IODEP study's findings, when considered within the broader literature context, provide important guidance for diabetes education practice and intervention design. The consistent identification of self-efficacy as the most influential factor suggests that interventions should prioritize confidence-building activities over knowledge transmission alone.

The literature on self-efficacy enhancement in diabetes education provides specific strategies that align with the IODEP study's findings. Mastery experiences, achieved through graduated skill-building activities and successful behavior implementation, appear to be the most powerful source of self-efficacy enhancement (Bandura, 1997). The IODEP study's emphasis on practical skill development and guided practice sessions likely contributed to the strong self-efficacy effects observed.

The social support findings suggest that interventions should focus on mobilizing support for specific diabetes management behaviors rather than general emotional support. The literature on family-based diabetes interventions provides models for engaging family members in specific supportive behaviors, such as medication reminders, meal planning assistance, and exercise companionship (Roland, 2012; Baig et al., 2015).

The patient involvement findings, while supported by emerging literature, suggest an area where more intervention development is needed. The literature on shared decision-making in diabetes care is still evolving, but the IODEP study's findings suggest that structured approaches to enhancing patient participation in treatment decisions may have meaningful clinical benefits.

5.9 Specific and Actionable Recommendations

These recommendations based on the IODEP study findings, addressing multiple levels of the healthcare system and providing concrete guidance for policymakers, healthcare administrators, and practitioners seeking to improve diabetes care in Ghana and similar low-income settings.

5.9.1 National Health Policy Recommendations

i. Integration of Structured Diabetes Education into National Health Insurance Scheme (NHIS). The IODEP study's demonstration of significant clinical improvements through structured diabetes education provides strong evidence for integrating such programmes into Ghana's National Health Insurance Scheme. Specific recommendations include:

   a. Coverage Expansion: The NHIS should be expanded to include coverage for structured diabetes education programs, with reimbursement rates that make these programmes financially viable for healthcare facilities.

   b. Standardized Protocols: The Ministry of Health should develop standardized protocols for diabetes education delivery based on the IODEP model, ensuring consistent quality across different healthcare facilities.

   c. Performance Metrics: NHIS reimbursement should be tied to specific performance metrics, including participant completion rates, HbA1c improvements, and patient satisfaction scores.

   d. Cost-Effectiveness Analysis: A formal cost-effectiveness analysis should be conducted to demonstrate the economic value of diabetes education programmes in reducing long-term healthcare costs through complication prevention.

ii. National Diabetes Education Curriculum Development. Based on the IODEP intervention's success, the Ministry of Health should develop a national diabetes education curriculum that can be implemented across Ghana's healthcare system:

   a. Modular Design: The curriculum should follow the IODEP's six-module structure, with standardized content that can be adapted to local contexts while maintaining core components.
   b. Cultural Adaptation Guidelines: Specific guidelines should be developed for adapting diabetes education content to different cultural and linguistic contexts within Ghana.
   c. Quality Assurance Standards: National standards should be established for diabetes education delivery, including facilitator qualifications, session duration, group size, and outcome monitoring requirements.
   d. Certification Program: A national certification programme should be established for diabetes educators, ensuring consistent competency levels across the country.

5.9.2 Healthcare System-Level Recommendations

i. Diabetes Care Delivery Model Transformation. The IODEP study's success suggests the need for fundamental changes in diabetes care delivery models in Ghana:

   a. Team-Based Care Implementation: Healthcare facilities should transition from physician-centered to team-based diabetes care models, incorporating diabetes educators, nutritionists, pharmacists, and community health workers.

b. Chronic Care Model Adoption: The Chronic Care Model should be formally adopted for diabetes management, with systematic approaches to patient self-management support, clinical information systems, and community resource utilization.

c. Care Coordination Systems: Formal care coordination systems should be established to ensure continuity between diabetes education programmes and routine clinical care.

d. Patient Registry Development: Comprehensive diabetes patient registries should be established to track patient outcomes, monitor programme effectiveness, and identify patients in need of additional support.

5.9.3 Regional and District-Level Implementation Strategies

i. Regional Diabetes Education Centers. Each region should establish specialized diabetes education centers that serve as hubs for programme delivery and training:

a. Center of Excellence Model: Regional centers should serve as centers of excellence for diabetes education, providing high-quality programmes and serving as training sites for healthcare providers from other facilities.

b. Outreach Programs: Regional centers should develop outreach programmes to provide diabetes education in rural and underserved areas, using mobile education units or satellite programs.

c. Resource Sharing: Regional centers should serve as resource sharing hubs, providing educational materials, equipment, and technical support to smaller healthcare facilities.

d. Quality Assurance: Regional centers should provide quality assurance oversight for diabetes education programmes in their catchment areas, including regular site visits and performance monitoring.

ii. Community Health Worker Integration. The IODEP study's success in improving social support suggests important roles for community health workers:

a. Training Programs: Comprehensive training programmes should be developed for community health workers to provide basic diabetes education and support in community settings.

b. Referral Systems: Formal referral systems should be established between community health workers and facility-based diabetes education programmes, ensuring appropriate patient identification and follow-up.

c. Peer Support Facilitation: Community health workers should be trained to facilitate peer support/self-help groups for diabetes patients, extending the social support benefits observed in the IODEP study.

d. Home Visit Programs: Structured home visit programmes should be developed to provide ongoing support for diabetes self-management, particularly for patients with transportation or mobility limitations.

5.10 Study Limitations and Critical Considerations

While this study provides valuable evidence for diabetes education effectiveness in sub-Saharan Africa, several important limitations must be acknowledged to enable critical assessment of the findings and their implications.

5.10.1 Design and Methodological Limitations

Quasi-Experimental Design Constraints: The study's quasi-experimental design, while necessary due to ethical and practical considerations, limits the ability to establish definitive

causal relationships between the intervention and observed outcomes (Schweizer et al., 2016). Participants were assigned to intervention or comparison groups based on hospital attendance rather than randomization, potentially introducing selection bias if patients attending different hospitals differed systematically in ways that could influence diabetes management outcomes, such as socioeconomic status, disease severity, or healthcare-seeking behaviors.

5.10.2 Measurement and Assessment Biases

Self-Report Bias: The study's reliance on self-reported measures for behavioral outcomes (self-management behaviors, dietary adherence, physical activity) introduces significant potential for social desirability bias and recall limitations (Althubaiti, 2016). Intervention participants, having received extensive diabetes education, may have been more likely to provide socially desirable responses or may have developed heightened awareness of "correct" behaviors, leading to overestimation of intervention effects (Schofield & Forrester-Knauss, 2013).

Hawthorne Effect: The intensive attention and monitoring that intervention participants received may have contributed to observed improvements through the Hawthorne effect, where individuals modify behavior simply because they know they are being observed (McCambridge et al., 2014). This effect may have inflated intervention benefits beyond what would be achieved in routine implementation settings.

Measurement Timing Sensitivity: The six-month follow-up period, while appropriate for detecting initial intervention effects, may have been insufficient to assess long-term sustainability of improvements or to capture delayed effects of some intervention components, particularly provider communication improvements (Nieuwlaat et al., 2014).

HbA1c measurements reflect 2-3-month averages, potentially missing short-term fluctuations that could provide insights into intervention mechanisms.

5.10.3 External Validity and Generalizability Concerns

Geographic and Cultural Specificity: The study was conducted in Northern Ghana with specific cultural, linguistic, and healthcare system characteristics that may limit generalizability to other regions of Ghana or other sub-Saharan African countries (Beaton et al., 2000). The intervention's cultural adaptations, while necessary for local effectiveness, may not translate directly to other cultural contexts without further modification.

Healthcare System Context: The study was implemented within Ghana's specific healthcare infrastructure and provider training context, which may limit transferability to countries with different healthcare delivery models, resource availability, or provider-patient relationship patterns (Glasgow et al., 2003). The intervention's effectiveness may depend on healthcare system characteristics that are not universally present across sub-Saharan Africa.

Participant Selection: Study participants were recruited from hospital-based diabetes clinics, potentially excluding individuals with diabetes who do not regularly access formal healthcare services or who receive care in different settings (primary health centres, private clinics). This selection may limit generalizability to the broader population of adults with diabetes in Ghana (Rothwell, 2005).

5.10.4 Implementation and Contamination Issues

Intervention Fidelity Variations: Despite high overall fidelity (>90%), some variations in intervention delivery across different groups and sessions may have affected the consistency of intervention effects, though these variations were systematically documented and analyzed (Bellg et al., 2004).

Potential Contamination: Although efforts were made to minimize contamination between study groups, some participants in the comparison group may have been exposed to intervention components through informal communication with intervention participants, family members, or healthcare providers, potentially reducing observed differences between groups (Torgerson, 2001).

5.10.5 Analytical Limitations

Intervention Fidelity Variation Unmeasured Confounding: Despite comprehensive assessment of multiple factors, unmeasured confounding variables (genetic factors, concurrent medical conditions, medication changes, life events) may have influenced outcomes and could not be controlled for in the analysis (Rothman et al., 2008).

Despite these limitations, the IODEP study provides the most rigorous evidence to date for diabetes education effectiveness in sub-Saharan Africa, with findings that are consistent across multiple outcome measures and theoretically coherent. The limitations identified provide important guidance for future research design and implementation planning rather than undermining the study's core contributions to diabetes care improvement in low-resource settings.

5.11 Study Strength

First, participants were largely from vulnerable groups comprising of illiterates, older people, and the unemployed, given diabetics equal opportunity to participate in the study. This contrasts with studies reviewed most of which only recruited participants who were educated, for example studies by Greenfield et al. (1985; 1988). Guided by the social cognitive theory, the study has given some insights into how intervention targeted at vulnerable T2DM patients can help improve control of the disease and patients' wellbeing.

Second, the intervention strategy (health education, support services, telephone calls, free HbA1c test for participants in both groups, rapport creation, among others) as well as the procedure adopted in rolling out the intervention helped in maintaining constant contact with, and in sustaining the interest of participants throughout the study. It also helped prevent contamination of both providers and study participants.

Third, the preparations given participants in the intervention group helped in reducing time spent in consultation during office visit as it provided clarity with regards to issues and concerns, they presented at each visit and the likely questions they want their providers to help address at each visit.

Fourth, the use of local/indigenous research assistants with knowledge of the local language, tradition, values, as well as the locality of participants helped during intervention implementation and data collection, among others. It allowed for quick establishment of rapport and free flow of information throughout the study.

Fifth, incorporating theoretical (SCT) frameworks into the study helped in strengthening the methodological robustness, efficacy, and practicality of the research process. Specifically, the use of the SCT allowed for the construction of a comprehensive conceptual framework, offering valuable insights into the personal, behavioural, and environmental factors that impact behaviour. The SCT versatility and extensive empirical support makes it an asset for researchers seeking to comprehend, predict, and modify human behaviour in various contexts.

5.12 Future Research

While the IODEP study makes important contributions to the literature, several limitations should be considered when interpreting the findings. The study's focus on a specific

population and intervention design may limit the generalizability of the findings to other contexts. The literature suggests that cultural, socioeconomic, and healthcare system factors may influence the relative importance of different factors for diabetes outcomes (Chlebowy et al., 2010; Nam et al., 2011).

The measurement approaches used in the IODEP study, while comprehensive, may not have captured all relevant dimensions of the constructs examined. The literature on diabetes self-efficacy, for example, suggests that domain-specific measures may be more predictive than general self-efficacy measures (Bijl et al., 1999). Future research should continue to refine measurement approaches to better capture the complexity of these relationships.

The temporal aspects of the relationships examined in the IODEP study also warrant further investigation. The literature suggests that the effects of different factors may vary over time, with some factors being more important for initial behavior change and others being more important for long-term maintenance (Rothman et al., 2011). Longer-term follow up studies are needed to understand these temporal patterns.

Furthermore, qualitative study could be conducted to delve into the lived experiences of vulnerable and low socioeconomic status patients with T2DM, specifically regarding their desire to participate in discussions with healthcare providers during office visits since existing literature is replete with information to the effect that vulnerable and low socioeconomic status patients with T2DM were reluctant to actively participate in discussions with their healthcare providers during office visits.

5.13 Summary of Key Findings and Conclusion

The IODEP intervention achieved remarkable success across multiple outcome domains, with the 1.8% reduction in HbA1c representing one of the largest improvements reported for

diabetes education interventions in sub-Saharan Africa. This clinical improvement was accompanied by significant enhancements in personal factors (15.4-point increase in self-efficacy, improved diabetes knowledge, enhanced patient involvement, and increased satisfaction with care), environmental factors (10.2-point improvement in social support), and behavioral factors (18.5% improvement in self-management practices). The regression analysis revealed that self-efficacy, dietary adherence, and physical activity were the strongest predictors of HbA1c reduction, validating the Social Cognitive Theory framework underlying the intervention design.

The magnitude and consistency of these improvements across multiple domains demonstrate the effectiveness of comprehensive, multi-component interventions that address the complex, interconnected factors influencing diabetes management. The study's success in achieving these outcomes in a resource-constrained setting provides compelling evidence that high-quality diabetes education can be delivered effectively in low-income countries when appropriate attention is paid to cultural adaptation, theoretical grounding, and systematic implementation.

5.13.1 Theoretical and Methodological Contributions

The IODEP study makes several important theoretical and methodological contributions to diabetes intervention research. First, the study provides strong empirical support for the application of Social Cognitive Theory to diabetes education in sub-Saharan African contexts, demonstrating that the theory's core constructs (personal, environmental, and behavioral factors) are relevant and actionable in this setting. The finding that self-efficacy emerged as the strongest predictor of clinical improvement reinforces the central importance of confidence-building in diabetes education interventions.

Second, the study demonstrates the feasibility and effectiveness of rigorous quasi-experimental research in low-resource settings, providing a methodological model for future intervention studies in similar contexts. The comprehensive process evaluation and fidelity assessment conducted as part of the study provide valuable insights into the implementation challenges and solutions that can inform future research and practice.

Third, the study's success in achieving high retention rates (>90%) and intervention fidelity (> 90%) in a challenging implementation environment demonstrates that complex behavioral interventions can be delivered with high quality in low-income settings when adequate attention is paid to cultural adaptation, staff training, and implementation support.

5.13.2 Clinical and Public Health Implications

The clinical implications of the IODEP study findings are substantial. The 1.8% reduction in HbA1c achieved through the intervention translates to meaningful reductions in diabetes-related complications, including approximately 38% reduction in diabetes-related deaths, 25% reduction in myocardial infarction risk, and 67% reduction in microvascular complications. In the context of Ghana's healthcare system, where resources for managing diabetes complications are limited, these preventive benefits represent significant value for both individual patients and the healthcare system.

From a public health perspective, the study demonstrates that relatively simple, low-cost educational interventions can have profound impacts on population health in resource-constrained settings. The intervention's group-based delivery model makes it highly scalable, with the potential to reach large numbers of diabetes patients efficiently. The study's success in mobilizing family and community support also suggests that diabetes education interventions can have broader community health benefits beyond their direct impact on participants.

The study's findings are particularly relevant given the rapidly increasing prevalence of diabetes in sub-Saharan Africa and the limited resources available for diabetes management in most countries in the region. The IODEP model provides a practical, evidence-based approach that can be adapted and implemented across diverse healthcare systems and cultural contexts.

5.14 Conclusion

The IODEP study represents more than just an evaluation of a diabetes education intervention; it demonstrates the potential for transforming diabetes care in low-income settings through systematic application of evidence-based approaches. The study's success in achieving substantial improvements in diabetes outcomes in a challenging implementation environment provides hope and practical guidance for healthcare systems struggling to address the growing burden of diabetes and other chronic diseases.

The comprehensive nature of the improvements achieved—spanning clinical, behavioral, and psychosocial domains—illustrates the power of theory-based, multi-component interventions that address the complex, interconnected factors influencing health behavior. The study's emphasis on building self-efficacy and mobilizing social support provides a model for empowering individuals and communities to take active roles in managing chronic diseases.

Perhaps most importantly, the IODEP study demonstrates that high-quality healthcare interventions can be delivered effectively in resource-constrained settings when adequate attention is paid to cultural adaptation, staff training, and systematic implementation. This finding has implications far beyond diabetes care, suggesting that many evidence-based interventions developed in high-income countries can be successfully adapted for implementation in low-income settings.

The path forward requires sustained commitment from policymakers, healthcare leaders, and the international community to invest in the infrastructure, workforce development, and system changes needed to scale effective interventions like IODEP. The evidence is clear that such investments can yield substantial returns in terms of improved health outcomes, reduced healthcare costs, and enhanced quality of life for millions of individuals living with diabetes in low-income countries.

The IODEP study provides a roadmap for this transformation, offering specific, actionable guidance for moving from evidence to implementation to population-level impact. The challenge now is to build on this foundation to create sustainable, scalable systems for diabetes education and management that can serve as models for other countries and other chronic diseases. The potential for impact is enormous, and the IODEP study provides both the evidence and the practical guidance needed to realize this potential.

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APPENDICES

Appendix I: Ghana Health Service Ethics Review

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Tel: +233-302-681109
Fax +233-302-685424
Email: ghserc@gmail.com

MyRef. GHS/RDD/ERC/Admin/App18/459
Your Ref. No.

14th December, 2020

Habibu Issah
SAHS
University for Development Studies (UDS)
P. O. Box TL 1883
Tamale

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC004/11/2020**
Project Title	Effect of Patients Active Involvement in the Management of Type 2 Diabetes Mellitus on Treatment Outcomes
Approval Date	14th December, 2020
Expiry Date	13th December, 2021
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings

1

Appendix I (cont.)

Please note that any modification of the study without ERC approval of the amendment is invalid

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol.

SIGNED .....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

Appendix II: Tools for Data Collection

INFORMED CONSENT FOR PRE-AND POST-CONSULTATION INTERVIEW WITH TYPE II DIABETICS

Interviewee:

Hello, good morning/afternoon/evening

Hello, my name is Issah Habibu and you are? (for courtesy, do not record responder's name)

I am a Doctor of Philosophy (PhD) student of the Faculty of Medicine and Health Sciences, University of Malaysia Sarawak. I am conducting a study entitled **"Effect of an Intensive Outpatient Diabetes Education Programme (IODEP) on Personal, Environmental, and Behavioural Factors, and Glycosylated Haemoglobin Levels in Ghanaians with Type 2 Diabetes"** with the purpose of establishing strategies to improve patient involvement in the management of their T2D disease and to assess its effect on patient control of their disease and health-related quality of life outcome, among others. You have been selected to participate in the study. You will self-complete a questionnaire or where necessary, I will ask questions about yourself and disease status, your level of involvement in treatment decision-making during consultation, your perceived social support received, knowledge of diabetes, decision-making self-efficacy, satisfaction with decision reached, including how you manage your disease at home (self-care management practices), level of control of the disease, and the effect of the disease on your quality of life, among others. I would like to assure you that your participation in this study will not affect the care you will receive in this facility. There is no compensation for your participation, however, the study may contribute to improvement in quality of care you will receive for your illness.

It will take about 30-45 minutes to complete the questionnaire/interview. Participation is however voluntary and you are liberty to withdraw from the study at any point in time you so desire. It is my hope however, that you will participate fully in the study because your views are very important. Any information provided will be kept strictly confidential and will be used only for purpose of this study.

Do you have any question before we start? (*Take few minutes to answer question(s) from respondents).*

Interviewer: do you agree to participate in this interview?

Respondent **agrees** to be interviewed	Signature or Thumbprint of respondent _____ Date: (/ /20)
Respondent do not agree to be interviewed	Reschedule interview? Yes/No If yes, date (/ /20) Time: ----------

Signature of interviewer: -------

Date: (/ /20)

Time started----------

Time ended----------

Name of facility: ……

Client folder number…… Next Clinic Visit…….

No.	DEMOGRAPHIC FACTORS	RESPONSES
1.	Age in completed years:	……..… (years)
2.	Sex:	[0] Female [1] Male
3.	Marital status:	[1] Never Married [2] Married [3] Widowed [4] Cohabiting [5] Divorced/ Separated
4.	Highest level of Education completed	[1] None [2] Primary/JHS [3] Secondary/SHS [4] Tertiary
5.	What religion are you affiliated to?	[1] Islam [2] Others (specify)……

No.	DEMOGRAPHIC FACTORS	RESPONSES
6.	What ethnic group do you belong to?	[1] Dagomba [2] Others (specify) ……
7.	Employment status:	[1] No employment, ***skip to Q9*** [2] Temporary employment [3] Permanent employment
8.	Have you ever received diabetes education?	[0] No [1] Yes
9.	HbA1c / FPG Level	…….
10.	How much do you earn monthly from your main occupation?	[1] Below Gh₵ 200 [2] Gh₵ 200 to Gh₵ 500 [3] Gh₵ 500 to Gh₵ 1000 [4] Above Gh₵ 1000
11.	Place of residence:	[1] Urban [2] Rural
12.	Do you have valid health insurance coverage? ***Inspect it.***	[0] No [1] Yes, ***skip to Q14***
13.	If no to **Q12**, is ability to afford health care treatment affect management and control of your diabetes?	[0] No [1] Yes
14.	Do you live alone?	[0] No [1] Yes
15.	How long have you lived with type 2 diabetes? ***In complete years.***	Years……
16.	Do you take medication for your diabetes?	[0] No [1] Yes
17.	If yes to **Q16** which one applies to you?	[1] Glucose lowering tablets [2] Insulin [3] Both
18.	Are you able to buy all your prescribed drugs?	[0] No [1] Yes
19.	Do you have any other health condition(s) apart from your diabetes? ***Hypertension, heart problem, cancer, etc.***	[0] No, ***skip to 21*** [1] Yes
20.	If yes to **Q19**, what other health condition(s) do you have?	State……
21.	How long do you have this provider attend to you during	[1] Less than 3 months [2] 4 – 12 months [3] 2 years

No.	DEMOGRAPHIC FACTORS	RESPONSES
	consultations? (duration of provider-patient relationship)	[4] Others (specify)……
22.	In general, how will you describe the way your provider communicates with you during today's or previous visits?	[1] Authoritarian, domineering and dismissive [2] Supportive and collaborative [3] Others (specify) ……
23.	How would you describe the environment during consultation with your provider?	[1] Noisy and unsupportive of healthy discussion [2] People walk in and out of provider's office [3] Provider engaged in discussion with other staff with little attention to me. [4] The environment provides privacy for discussion
	HEALTH FACILITY VISIT	
24.	How many times have you visited this particular facility in the past 12 months with your diabetes?	
25.	Have you visited some other health facility/facilities with your diabetes in the past 12 months?	[0] No, ***Skip to Q33.*** [1] Yes
26.	If yes to **Q31**, name of health facility/facilities.	……..
27.	Have you ever visited the traditional healer in the past 12 months in connection with your diabetes?	[0] No, ***Skip to Q35.*** [1] Yes
28.	If **yes to Q33** how many times have you visited the traditional healer in the past 12 months?	……..…
29.	How long have you been in this health facility today? ***Time spent***	……..… (minutes)
30.	Do you feel that you have spent too much time in the facility today?	[1] No [2] Yes
31.	If **yes** to **Q 36,** what do you think might have caused your delay in the facility	[1] Many clients for providers to attend to. [2] Limited number of providers available. [3] Others (specify) ……

No.	DEMOGRAPHIC FACTORS	RESPONSES				
	Section B: Involvement Indicators Scale. *Below is a set of statement about your perception of your involvement in treatment decision-making process. Please read each item carefully and relate them to the current clinical encounter you had with the provider. On the scale of 1 to 5 select your level of agreement with each item where:* **[1] Never (N); [2] Little of the time (LT); [3] Some of the time (ST); [4] Most of the time (MT); [5] Always (A)**					
	Patient Involvement	**N**	**LT**	**ST**	**MT**	**A**
[B1]	Decisions about my treatment are taken in collaboration with me.	[1]	[2]	[3]	[4]	[5]
[B2]	Providers actively create chances for patient participation in decision-making.	[1]	[2]	[3]	[4]	[5]
[B3]	I am treated as an equal conversation partner during consultation.	[1]	[2]	[3]	[4]	[5]
[B4]	I receive tailored information that do not provide room for my participation.	[1]	[2]	[3]	[4]	[5]
[B5]	My opinion is considered important in the care process.	[1]	[2]	[3]	[4]	[5]
[B6]	The end decision about my treatment is taken by me.	[1]	[2]	[3]	[4]	[5]
[B7]	My strengths and weaknesses are considered equally.	[1]	[2]	[3]	[4]	[5]

	Section C: Social Support Received. *Social support received by patients is a very important part of patient involvement in the management of T2D. We would like to know how you rate the social support received for participation in managing your disease during office visit. On the scale of 1 to 4 select your level of agreement with each item where*: **[1] Never (N); [2] Rarely (R); [3] Sometimes (ST); [4] Often (O).**				
	How frequently have you received social support for/related to…?	**N**	**R**	**ST**	**O**
[B8]	… planning treatment goals	[1]	[2]	[3]	[4]
[B9]	… a set of specific skills and strategies necessary to engage providers during office visits	[1]	[2]	[3]	[4]

B10]	…keeping these goals, skills and strategies to engage providers during office visits	[1]	[2]	[3]	[4]
B11]	…identifying and reducing barriers to engage providers during office visits	[1]	[2]	[3]	[4]
B12]	…how to negotiate treatment options with providers	[1]	[2]	[3]	[4]
B13]	…engaging providers in discussing risks and benefits associated with treatment options	[1]	[2]	[3]	[4]

Section D: The Spoken Knowledge in Low Literacy in Diabetes (SKILLD) Knowledge Assessment Scale.

It is an instrument developed to assess core patient knowledge about diabetes self-care issues, including glucose management, appropriate lifestyle modifications, the recognition and treatment of acute complications, and appropriate activities to prevent long-term consequences of uncontrolled disease. ***Write your response in the space provided****.*

B14]	What are the signs and symptoms of high blood sugar? *How do you feel when your blood sugar is high or when you were diagnosed?*	
B15]	What are the signs and symptoms of low blood sugar? *How do you feel when your blood sugar is too low?*	
B16]	How do you treat low blood sugar? *What should you do if your sugar is too low? How can you bring your blood sugar up if it's too low?*	
B17]	How often should a person with diabetes check his or her feet? *Once a day, once a week, or once a month?*	
B18]	Why are foot exams important in someone with diabetes? *Why is it important to look at your feet? What are you looking for?*	

B19]	How often should you see an eye doctor and why is it important? *How often? Why?*	
B20]	What is a normal fasting blood glucose or blood sugar? *When you get up first thing in the morning and check your blood sugar before you eat or take medicine, what should it be? What 2 numbers?*	
B21]	What is a normal HbA1c (haemoglobin A1C) or "average blood sugar test"? *When they draw blood from your arm and get an average blood sugar reading, what should it be?*	
B22]	How many times per week should someone with diabetes exercise and for how long? *How many times a week? How long or how much per day?*	
B23]	What are some long-term complications of uncontrolled diabetes? *Do you know anyone that has diabetes and had "bad things" happen to them? What are some of those "bad things"?*	

Section E: Decision-Making Self-Efficacy Scale.

The 'Decision Self-Efficacy *Scale' measures self-confidence or belief in one's abilities to participate in decision-making, including shared decision-making. Below are listed some things involved in making an informed choice. Please show how confident you feel in doing these things by circling the number from:*

[1] & [2] Not at all confident (NC); [3] Somehow confident (S);
[4] Confident (C); [5] Very confident (VC).

	I feel confident that I can…	**NC**	**NC**	**S**	**C**	**VC**
B24]	engage my provider in reaching treatment choices available to me.	[1]	[2]	[3]	[4]	[5]
B25]	impress upon my provider to discuss with me about the benefits of each choice.	[1]	[2]	[3]	[4]	[5]
B26]	impress upon my provider to discuss with me about risks and side effects of each choice made.	[1]	[2]	[3]	[4]	[5]
B27]	understand the information enough to be able to make a choice.	[1]	[2]	[3]	[4]	[5]
B28]	ask questions without feeling dumb or intimidated.	[1]	[2]	[3]	[4]	[5]

B29]	express my concerns about each choice.	[1]	[2]	[3]	[4]	[5]
	I feel confident that I can…	**NC**	**NC**	**S**	**C**	**VC**
B30]	ask for advice.	[1]	[2]	[3]	[4]	[5]
B31]	figure out the choices that best suits me.	[1]	[2]	[3]	[4]	[5]
B32]	handle unwanted pressure from others in making my choice.	[1]	[2]	[3]	[4]	[5]
B33]	let the clinic team know what is best for me.	[1]	[2]	[3]	[4]	[5]
B34]	delay my decisions if I feel I need more time.	[1]	[2]	[3]	[4]	[5]
	Section F: Satisfaction with Decision Sub-Scale of Clinical Decision-Making Involvement and Satisfaction-patient-rated (CDIS-P). *Please provide an answer for each item by ticking a box that gives the best answer for you. On the scale of 1 to 5 select your level of agreement with each statement where* **[1] Strongly disagree (SD); [2] Disagree (D); [3] Uncertain (U);** **[4] Agree (A); [5] Strongly agree (SA)**					
	Please indicate to what extent each statement is TRUE for you AT THIS TIME:	**SD**	**[D**	**U**	**A**	**SA**
B35]	I am satisfied that I am adequately informed about the issues important to **the** decision to be made about my treatment.	[1]	[2]	[3]	[4]	[5]
B36]	I am satisfied that the decision we (myself and my provider) made was the best decision possible in my view.	[1]	[2]	[3]	[4]	[5]
B37]	I am satisfied that **the** decision was consistent with my personal values.	[1]	[2]	[3]	[4]	[5]
B38]	I expect the decision we made to be successfully acted on/continued to be acted on.	[1]	[2]	[3]	[4]	[5]
B39]	I am satisfied that this was the decision to make.	[1]	[2]	[3]	[4]	[5]
B40]	I am satisfied with **the** decision.	[1]	[2]	[3]	[4]	[5]
	Section G: Communication Assessment Tool. *Communication with patients is a very important part of quality medical care. We would like to know how you feel about the way your provider communicated with you. Your answers are completely confidential, so please be as open and honest as you can. On the scale of 1 to 5 select your level of agreement with each statement where:*					

	[1] Poor (P); [2] Fair (F); [3] Good (G); [4] Very good (VG); [5] Excellent (E*).*					
	The provider…	**P**	**F**	**G**	**VG**	**E**
B41]	Greeted me in a way that made me feel comfortable.	[1]	[2]	[3]	[4]	[5]
B42]	Treated me with respect.	[1]	[2]	[3]	[4]	[5]
B43]	Showed interest in my views about my health.	[1]	[2]	[3]	[4]	[5]
	The provider…	**P**	**F**	**G**	**VG**	**E**
B44]	Understood my main health concerns.	[1]	[2]	[3]	[4]	[5]
B45]	Paid attention to me (looked at me, listened carefully).	[1]	[2]	[3]	[4]	[5]
B46]	Let me talk without interruptions.	[1]	[2]	[3]	[4]	[5]
B47]	Gave me as much information as I wanted.	[1]	[2]	[3]	[4]	[5]
B48]	Talked in terms I could understand.	[1]	[2]	[3]	[4]	[5]
B49]	Checked to be sure I understood everything discussed.	[1]	[2]	[3]	[4]	[5]
B50]	Encouraged me to ask questions.	[1]	[2]	[3]	[4]	[5]
B51]	Involved me in decisions as much as I wanted.	[1]	[2]	[3]	[4]	[5]
B52]	Discussed next steps, including any follow-up plans.	[1]	[2]	[3]	[4]	[5]
B53]	Showed care and concern.	[1]	[2]	[3]	[4]	[5]
B54]	Spent the right amount of time with me.	[1]	[2]	[3]	[4]	[5]
	Section H: Diabetes Self-Management Questionnaire (DSMQ*)* *It is an instrument used to assess diabetes self-care activities associated with glycaemic control. Provide an answer for each question by ticking a box that gives the best response. On the scale of 1 to 5 select your level of agreement with each statement where:* **[3] Applies to me very much (AVM); [2] Applies to me to a considerable degree (ACD); [1] Applies to me to some degree (ASD); [0] Does not apply to me (DAM*).***					
	The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you	**AVM**	**ACD**	**ASD**	**DAM**	
B55]	I check my blood sugar levels with care and attention. ☐ Blood sugar measurement is not required as a part of my treatment.	[3]	[2]	[1]	[0]	
B56]	The food I choose to eat makes it easy to achieve optimal blood sugar levels.	[3]	[2]	[1]	[0]	

B57]	I keep all doctors' appointments recommended for my diabetes treatment.	[3]	[2]	[1]	[0]
B58]	I take my diabetes medication (e. g. insulin, tablets) as prescribed. ☐ *Diabetes medication / insulin is not required as a part of my treatment*.	[3]	[2]	[1]	[0]
B59]	Occasionally, I eat lots of sweets or other foods rich in carbohydrates.	[3]	[2]	[1]	[0]
	The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the last 8 weeks, please specify the extent to which each statement applies to you	**AVM**	**ACD**	**ASD**	**DAM**
B60]	I record my blood sugar levels regularly (or analyze the value chart with my blood glucose meter). ☐ *Blood sugar measurement is not required as a part of my treatment*.	[3]	[2]	[1]	[0]
B61]	I tend to avoid diabetes-related doctors' appointments.	[3]	[2]	[1]	[0]
B62]	I do regular physical activity to achieve optimal blood sugar levels.	[3]	[2]	[1]	[0]
B63]	I strictly follow the dietary recommendations given by my doctor or diet therapist/specialist.	[3]	[2]	[1]	[0]
B64]	I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control. ☐ *Blood sugar measurement is not required as a part of my treatment.*	[3]	[2]	[1]	[0]
B65]	I avoid physical activity, although it would improve my diabetes.	[3]	[2]	[1]	[0]
B66]	I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets). ☐ *Diabetes medication / insulin is not required as a part of my treatment.*	[3]	[2]	[1]	[0]
B67]	Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	[3]	[2]	[1]	[0]
B68]	Regarding my diabetes care, I should see my medical practitioner(s) more often.	[3]	[2]	[1]	[0]

B69]	I tend to skip planned physical activity.	[3]	[2]	[1]	[0]
B70]	My diabetes self-care is poor.	[3]	[2]	[1]	[0]

Appendix III: Module for the Intensive Outpatient Diabetes Education Programme (IODEP)

Overview

The Intensive Outpatient Diabetes Education Programme (IODEP) curriculum comprises eight structured modules designed to enhance diabetes self-management capabilities among Type 2 diabetes patients in Ghana. Each module addresses specific aspects of diabetes care through evidence-based educational strategies adapted to improve disease control among diabetics.

Module Summary Table

Module	Title	Duration	Primary Focus	Target Competencies
1	Introduction to Type 2 Diabetes	2 hours	Disease understanding	Knowledge foundation
2	Blood Sugar Monitoring	2 hours	Glucose management	Technical skills
3	Medications and Insulin Therapy	2 hours	Pharmacological management	Medication competency
4	Nutrition and Meal Planning	2 hours	Dietary management	Nutritional skills
5	Physical Activity	2 hours	Exercise integration	Activity planning
6	Preventing Complications	2 hours	Complication prevention	Preventive care
7	Coping and Psychosocial Aspects	2 hours	Emotional management	Psychological support
8	Practical Skills and Self-Management	2 hours	Integration and application	Comprehensive self-care

Detailed Module Structure

Module 1: Introduction to Type 2 Diabetes

Component	Details
Educational Objectives	Establish foundational knowledge of Type 2 diabetes pathophysiology, classification, and clinical presentation within Ghanaian cultural contexts
Core Topics	• Understanding Diabetes: Definition and types • Pathophysiology of Type 2 Diabetes • Risk factors and causes • Symptoms and diagnosis
Learning Outcomes	• Define Type 2 diabetes and distinguish from other types • Explain biological mechanisms behind Type 2 diabetes • Identify risk factors and common symptoms • Understand diagnostic criteria and tests
Teaching Methods	Interactive discussions.
Assessment	Knowledge quiz, symptom identification exercise
Cultural Adaptations	Local dietary examples, Ghanaian health beliefs integration

Module 2: Blood Sugar Monitoring

Component	Details
Educational Objectives	Develop practical competencies in glucose monitoring techniques and interpretation of results for effective diabetes self-management
Core Topics	• Importance of blood glucose monitoring • Types of blood glucose monitors • How to use a glucometer • Target blood glucose levels • Recording and interpreting results
Learning Outcomes	• Understand why blood glucose monitoring is crucial • Learn proper use of different glucometer types • Identify target glucose levels for different times • Develop skills to record and interpret readings
Teaching Methods	Hands-on demonstrations, practice sessions.
Assessment	Practical demonstration, log book review
Resources Required	Glucometers, test strips, lancets, log books

Module 3: Medications and Insulin Therapy

Component	Details
Educational Objectives	Provide comprehensive understanding of pharmacological interventions, administration protocols, and adherence strategies for diabetes management
Core Topics	• Overview of oral medications for Type 2 diabetes • Introduction to insulin therapy • Medication schedules and adherence • Managing side effects
Learning Outcomes	• Gain knowledge about different oral medications • Understand insulin therapy applications • Learn medication scheduling and adherence importance • Recognize and manage medication side effects
Teaching Methods	Medication samples, adherence planning
Assessment	Medication identification, adherence plan development
Safety Considerations	Proper storage, disposal, emergency procedures

Module 4: Nutrition and Meal Planning

Component	Details
Educational Objectives	Establish evidence-based nutritional principles incorporating culturally appropriate food choices and preparation methods for Ghanaian dietary patterns
Core Topics	• Principles of healthy eating for diabetes • Carbohydrate counting and glycemic index • Meal planning and portion control • Reading food labels

Component	Details
Learning Outcomes	• Understand diabetes-friendly diet principles • Learn carbohydrate counting and glycemic index • Develop meal planning and portion control skills • Learn to read and understand food labels
Teaching Methods	Food models, portion demonstrations, meal planning exercises
Assessment	Meal plan creation, portion size identification
Local Adaptations	Traditional Ghanaian foods, local market foods, cultural preferences

Module 5: Physical Activity

Component	Details
Educational Objectives	Emphasize therapeutic role of physical activity in diabetes management with safety considerations and practical implementation strategies
Core Topics	• Benefits of physical activity for diabetes management • Types of recommended exercises • Creating an exercise plan • Safety tips and precautions • Managing blood sugar levels during exercise
Learning Outcomes	• Understand benefits of regular physical activity • Learn about suitable exercise types for diabetes • Develop personalized exercise plan • Identify safety tips and precautions • Learn blood sugar management during exercise
Teaching Methods	Exercise demonstrations, activity planning, safety briefings

Component	Details
Assessment	Personal exercise plan development, safety protocol quiz
Adaptations	Climate considerations, available facilities, cultural activities

Module 6: Preventing Complications

Component	Details
Educational Objectives	Address long-term diabetes complications through preventive strategies and early detection protocols
Core Topics	• Common complications of Type 2 diabetes • Foot care and preventing neuropathy • Eye care and preventing retinopathy • Cardiovascular health • Regular screenings and check-ups
Learning Outcomes	• Identify common diabetes complications • Learn foot care and neuropathy prevention • Understand importance of regular eye care • Recognize cardiovascular health importance • Develop schedule for regular screenings
Teaching Methods	Demonstration of care techniques, screening schedules
Assessment	Care routine demonstration, screening schedule creation
Healthcare Integration	Local healthcare services, referral pathways, screening availability

Module 7: Coping and Psychosocial Aspects

Component	Details
Educational Objectives	Address psychological dimensions of diabetes management and social support system development within Ghanaian cultural contexts
Core Topics	• Emotional impact of diabetes • Stress management techniques • Building a support system • Dealing with diabetes-related depression and anxiety • Resources for mental health support
Learning Outcomes	• Understand emotional and psychological impact • Learn effective stress management techniques • Recognize importance of building support systems • Identify signs of depression and anxiety • Access resources for mental health support
Teaching Methods	Group discussions, support/self-help groups formation
Assessment	Stress management plan, support network mapping
Cultural Sensitivity	Traditional healing practices, family dynamics, community support

Module 8: Practical Skills and Self-Management

Component	Details
Educational Objectives	Integrate knowledge from previous modules into comprehensive self-management competencies and sustainable self-care routines
Core Topics	• Self-monitoring and self-care routines

Component	Details
	• Developing a diabetes action plan • Problem-solving for high and low blood sugar • Accessing community resources
Learning Outcomes	• Develop comprehensive self-monitoring routines • Create personalized diabetes action plan • Learn problem-solving strategies for glucose management • Identify and access community resources
Teaching Methods	Action plan development, problem-solving scenarios, questions asking techniques
Assessment	Comprehensive action plan, problem-solving exercises
Sustainability	Long-term planning, ongoing support

Implementation Framework

Implementation Component	Description	Timeline	Responsible Party
Interactive Sessions	Discussion-based learning, Q&A sessions, hands-on demonstrations	2 hours per module	PI and his Research Assistants
Individual Counseling	Personalized guidance based on individual needs and circumstances	30 minutes per participant	PI and his Research Assistants
Follow-Up Sessions	Periodic assessment and interactions adjustment based on feedback	Monthly for 6 months	PI and his Research Assistants

Implementation Component	Description	Timeline	Responsible Party
Resource Materials	Educational information, demonstration materials, monitoring tools	Ongoing	PI and his Research Assistants

Assessment and Evaluation Framework

Assessment Type	Method	Frequency	Purpose
Knowledge Assessment	Pre/post module quizzes	Each module	Measure learning outcomes
Practical Skills	Hands-on demonstrations	Modules 2, 3, 4, 5, 8	Evaluate technical competencies
Behavioral Change	Self-monitoring logs	Weekly	Track self-management practices
Clinical Outcomes	HbA1c, glucose logs	3-monthly	Measure programme effectiveness
Programme Evaluation	Participant feedback	End of programme	Continuous improvement

Resource Requirements

Resource Category	Specific Items	Quantity	Purpose
Educational Materials	Visual aids, flipcharts	Per participant	Knowledge delivery
Monitoring Equipment	Glucometers, test strips, lancets	Per group	Practical training

Resource Category	Specific Items	Quantity	Purpose
Demonstration Tools	Food models, portion plates, exercise equipment	Per session	Skills development
Documentation	Log books, action plan templates	Per participant	Self-management tracking
Technology	Projector, laptop, speakers	Per venue	Presentation delivery

Programme Effectiveness Indicators

Indicator Category	Specific Measures	Target Outcomes	Measurement Method
Knowledge Improvement	Pre/post test scores	60-70% improvement among intervention participants	Standardized assessments
Skill Development	Practical competencies	60-70% proficiency	Practical demonstrations
Behavioral Change	Self-management practices	60-70% adherence	Self-monitoring logs
Clinical Outcomes	HbA1c reduction	1% average reduction	Laboratory tests

Cultural Adaptations

Adaptation Area	Specific Modifications	Rationale
Language	Local language integration, simplified terminology	Enhance comprehension and accessibility

Adaptation Area	Specific Modifications	Rationale
Dietary Content	Traditional Ghanaian foods, local ingredients	Cultural relevance and practical application
Social Context	Family involvement & support emphasis	Align with Ghanaian social structures
Healthcare System	Local healthcare service integration	Ensure continuity of care

The IODEP educational modules represent a comprehensive, culturally adapted educational framework designed to enhance diabetes self-management capabilities among Type 2 diabetes patients in Ghana. The structured eight-module approach addresses essential knowledge domains while incorporating practical skills development, psychosocial support, and community resource utilization.

The tabular presentation facilitates systematic implementation, assessment, and evaluation of the programme components. This framework provides clear guidelines for delivering effective diabetes education that is both evidence-based and culturally appropriate for the Ghanaian context.

The modular design ensures flexibility in implementation while maintaining educational rigor and measurable outcomes. The integration of assessment frameworks, among others supports long-term programme success and scalability within Ghana's healthcare system.

Appendix IV: Target for Information Sharing Session

Target for Information Sharing Session

Options to engage providers with during consultation to achieve better self-management of your diabetes.

Name: _____

Date: _____

Agreements:

- The circle includes a variety of self-management skills … they ALL may be highly important to your health, but you don't need to do ALL of them ALL the time.
- If there is a topic that is more important to you, add it to the circle.
- Nobody does all of these perfectly.
- It is best to work on one or two at a time.
- This is a partnership. You will not be pushed.
- You choose which one(s) you want to discuss in your next visit with your provider and develop your GOAL and PLAN on it.

Checking Blood Sugar Physical Activity

Eating: food choices, portion sizes, time of day Referrals

Fatigue

Foot Care Eye care Weight Loss

Regular Visits Taking Medicine

Smoking Drinking

Managing: Hyperglycemia
Hypoglycemia

Living with Comorbid Conditions

The steps outlined below give an interactive feedback loop between research team and patients.

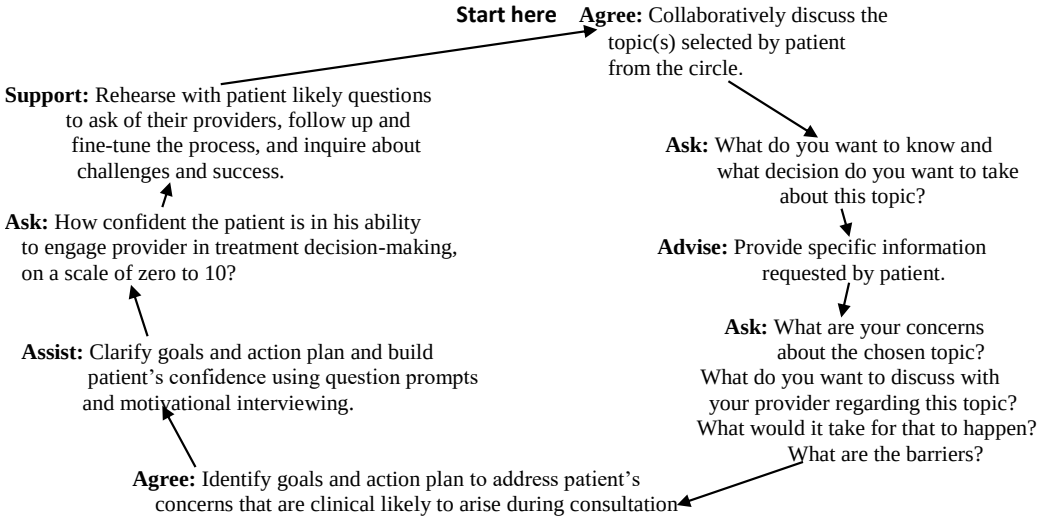

Figure 3.2. Target practice: a tool to guide information sharing session between research assistants' intervention participants. Modified from Coleman and Newton, 2005.

Appendix V: Health Changes Plan

HEALTHY CHANGES PLAN

Name: _____ Date: _____

Phone: _____

The healthy change I want to make is:

My goal for the next month is:

The steps I will take to achieve my goal are (what, when, where, how much, how often):

The things that could make it difficult to achieve my goal include:

My plan for overcoming these difficulties includes:

Support/resources I will need to achieve my goal include:

My confidence level (scale of 1-10, 10 being completely confident that you can achieve the entire plan) _____

Review date: _____

Review method (phone, email, in-person): _____

Appendix VI: Question to Ask Your Doctor and Diabetes Care Team

QUESTIONS TO ASK YOUR DOCTOR AND DIABETES CARE TEAM

Living with type 2 diabetes can be difficult, but you can manage living with it. The best place to turn if you have questions, is your providers. Do not shy away from asking questions. Questions may help you start or continue a dialogue with your provider about managing diabetes. Remember, your providers are there to help.

As a patient, you can make your care safer by being an active, involved and informed member of your health care team. Evidence established that medical mistakes are a serious problem in the health care system. It is generally agreed that patients should be involved in their own health care, and research shows that patients who take part in decisions about their own health care are more likely to get better faster. To help prevent health care mistakes and improve quality of health care, patients are urged to participate in their medical care process. Hence, at every visit, you may ask any of the following questions to ensure that you receive appropriate care for your diabetes.

Blood Sugar Questions

What should my blood sugar levels be?

How often and when should I check my blood sugar level at home? How do I use my meter?

How do I know if my blood sugar is too low? How do I know if it is too high?

What should I do if it is too low or too high?

ABCs (A1C, Blood Pressure, Cholesterol, and Smoking Cessation) Questions

What are the ABCs of type 2 diabetes?

Appendix VI (cont.)

What should my ABC numbers be?

What can I do to help reach these numbers?

Exercise Questions

Before I start exercising, do I need to have my heart checked out? My eyes? My feet?

What type of exercise program should I follow? What types of activities should I avoid?

How can exercise affect my blood sugar?

How should I watch my blood sugar when I exercise?

What should I bring with me when I exercise?

Nutrition Questions

What kinds of nutritional guidelines should I be following?

Can I still eat foods that I love?

Are there foods and drinks I should not have?

Medication Questions

What medication(s) do I need to take for my diabetes, if any?

Appendix VI (cont.)

How does this work? How will this help me?

When should I take them?

What should I do if I miss a dose?

Are there any side effects? What should I do if I experience a side effect?

Are there any other special instructions that I should know, such as taking them with food?

How should I store my medications?

Foot and Skin Care Questions

Why is it important to check my feet? How often should I check my feet?

What should I do when I check them?

What problems should I call my doctor or nurse about?

Who should trim my toenails? Is it okay if I trim them?

How should I take care of my feet every day?

Other Care Plan Questions

Are there other doctors or healthcare professionals I should visit?

Appendix VI (cont.)

Are there certain tests that I need to get done and when?

Why is it important to check my eyes? When should I have a doctor check my eyes?

When should I schedule my next appointment?

Other Important Questions

• How could weight loss affect my type 2 diabetes?

• What happens if changing my diet and exercising aren't enough to control my blood sugar?

• How can type 2 diabetes affect my heart?

• What if my cholesterol is elevated?

• How can type 2 diabetes affect my vision?

• What kind of eye problems should I be aware of?

• How often should I have an eye exam?

• How can type 2 diabetes affect my kidneys?

• How often should my kidney function be tested?

• How often should I check my feet, and what—if anything— should I be looking for?

• How can I help myself be less depressed about having type 2 diabetes?

• I haven't exercised in a long time. What should I do?

• How often should I exercise and for how long?

• What is the best time of day to exercise?

• I have a new prescription. Will it interact with the things I am already taking?