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DEVELOPMENT OF A SELF-REGULATION MODEL BASED ON FAMILY CENTERED NURSING WITH AN EXPERIENTIAL LEARNING APPROACH ON QUALITY OF LIFE IN TYPE 2 DIABETES MELLITUS PATIENTS

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ABSTRACT
Type 2 diabetes mellitus (T2DM) remains a major global non-communicable disease associated with persistent glycemic dysregulation, complications, and reduced quality of life. Existing diabetes education programs often emphasize knowledge transfer but provide limited integration of family involvement, emotional responses, and experiential learning in sustaining self-regulation. This study aimed to develop and validate a self-regulation model based on Family-Centered Nursing (FCN) and Experiential Learning (EL) for patients with T2DM. A three-phase explanatory research design was employed. Phase 1 involved a cross-sectional study of 155 patients analyzed using Structural Equation Modeling–Partial Least Squares (SEM-PLS) to identify determinants of self-regulation and quality of life. Phase 2 focused on module development through focus group discussions, expert consultation, and content validity assessment. The structural model demonstrated strong explanatory power for self-regulation ($R^2 = 0.867$) and quality of life ($R^2 = 0.807$). Patient factors, family factors, family support, and health service quality significantly influenced self-regulation and quality of life. A sequential pathway was also identified in which patient factors influenced disease representation, which subsequently affected emotional responses, self-regulation, and quality of life. Family support showed the strongest direct effect on quality of life, while patient factors were the strongest predictor of self-regulation. The developed FCN-EL module achieved an overall Content Validity Index of 1.00. These findings establish an integrated FCN-EL self-regulation model that links individual, family, emotional, and health service factors within a unified framework for T2DM management.

KEYWORDS: type 2 diabetes mellitus; self-regulation; family-centered nursing; experiential learning; quality of life; glycemic control; SEM-PLS; Indonesia

1. INTRODUCTION
Type 2 diabetes mellitus (T2DM) represents one of the most prevalent and economically burdensome non-communicable diseases of the twenty-first century. The International Diabetes Federation estimated that 537 million adults were living with diabetes globally in 2021, with projections indicating an increase to 643 million by 2030 and 783 million by 2045 (International Diabetes Federation, 2023). In Indonesia, T2DM accounts for approximately 90% of all diabetes cases, yet glycemic control remains deeply suboptimal: national data indicate that over 50% of T2DM patients fail to achieve the American Diabetes Association's recommended HbA1c target of below 7% (BPJS Kesehatan, 2020). At the local level, surveillance data from the Pontianak City Health Office revealed that many patients continue to hold misconceptions about their condition, with a substantial proportion believing that pharmacological therapy alone is sufficient for blood glucose management (Dinas Kesehatan

Kota Pontianak, 2024). This misconception reflects a deeper systemic failure in patient empowerment and self-management education.

The consequences of inadequate self-regulation in T2DM are multi-dimensional and severe. Uncontrolled hyperglycemia drives progressive microvascular and macrovascular complications, including neuropathy, nephropathy, retinopathy, coronary artery disease, and peripheral vascular disease (Saeedi & others, 2019). These complications translate directly into reduced functional capacity, psychological distress, and impaired social participation, collectively diminishing the patient's quality of life (QoL). Epidemiological studies in Indonesia report that 74.2% of T2DM patients present with poor QoL (Nisa & Kurniawati, 2022), while 41.6% to 56.8% of patients demonstrate inadequate glycemic control (Dinavari & others, 2023; Shita & others, 2022). Beyond clinical outcomes, the socioeconomic burden is substantial, as diabetes-related disability and healthcare utilization impose significant costs on individuals, families, and health systems (Haryanto & others, 2023).

Current diabetes management frameworks, including Diabetes Self-Management Education and Support (DSMES) programs, have demonstrated efficacy in improving patient knowledge and skills; however, their real-world effectiveness is constrained by several structural limitations. Conventional DSMES approaches are predominantly didactic, information-centric, and unidirectional, focusing on knowledge transmission without adequately fostering experiential integration, reflective practice, or behavioral sustainability (Chrvala et al., 2016; Pamungkas et al., 2017). Moreover, these programs rarely incorporate the patient's immediate social environment, particularly the family, as an active therapeutic partner. Evidence consistently demonstrates that family involvement in diabetes management is associated with better adherence to self-care behaviors, improved glycemic outcomes, and higher QoL (Fadli & others, 2024; Polsook & others, 2023). Yet, a structured, theoretically grounded intervention model that systematically integrates family-centered nursing principles with experiential learning methodology for T2DM self-regulation has not been previously developed or empirically tested.

This study addresses this gap through the development and validation of the Family-Centered Nursing Experiential Learning (FCN-EL) self-regulation model. The model draws upon four complementary theoretical frameworks: (Ogden, 2007)health psychology model of self-regulation, Leventhal's Common-Sense Model of Self-Regulation (Cameron & Leventhal, 2012), Friedman's Family-Centered Nursing model (Friedman et al., 2003), and Kolb's Experiential Learning Theory (Kolb, 2015). By synthesizing these frameworks, the FCN-EL model targets the cognitive, emotional, familial, and experiential determinants of self-regulation and QoL within a unified, implementable structure.

The study was conducted in three sequential phases. Phase 1 employed SEM-PLS to empirically identify and quantify the structural relationships among patient factors, family factors, family support, health service quality, disease representation, emotional response, self-regulation, and quality of life. Phase 2 translated these empirical findings into a structured educational module through a participatory development process involving patients, nurses, and clinical experts. Phase 3, to be reported separately, will evaluate the module's effectiveness on QoL and glycemic control (fasting blood glucose and HbA1c) through a quasi-experimental randomized controlled trial. This paper reports the Phase 1 and Phase 2 findings and the theoretical integration underpinning the FCN-EL model.

2. LITERATURE REVIEW

2.1. Type 2 Diabetes Mellitus

Type 2 Diabetes Mellitus is a metabolic disorder characterized by chronic hyperglycemia resulting from insulin resistance and relative insulin deficiency (Mishra, 2020; Tran Nguyen, 2024). Unlike Type 1 diabetes, T2DM typically develops gradually and is strongly associated with modifiable risk factors, including obesity, physical inactivity, unhealthy dietary patterns, and genetic predisposition (Nusdin, 2023). The pathophysiology involves progressive beta-cell

dysfunction and peripheral insulin resistance, leading to impaired glucose uptake in muscle and adipose tissue while hepatic glucose production remains elevated.

Diagnosis follows American Diabetes Association criteria: fasting plasma glucose ≥126 mg/dL, 2-hour post-load glucose ≥200 mg/dL during oral glucose tolerance test, random glucose ≥200 mg/dL with classic symptoms, or HbA1c ≥6.5% (Ortiz-Martinez et al., 2022). Complications are categorized as acute (hypoglycemia, hyperglycemic crises), microvascular (nephropathy, retinopathy, neuropathy), and macrovascular (coronary artery disease, stroke, peripheral arterial disease), all of which significantly impair QoL (Saputri, 2020).

2.2. Self-Regulation Theory

Self-regulation is broadly defined as the internal psychological processes through which individuals monitor, evaluate, and adjust their thoughts, emotions, and behaviors in pursuit of health-related goals (Cameron & Leventhal, 2012). In chronic disease contexts, self-regulation has emerged as a central construct linking patients' understanding of their illness with their health behaviors and outcomes. (Ogden, 2007) problem-solving model of self-regulation identifies three core processes: interpretation of a health threat, adoption of a coping strategy, and appraisal of coping effectiveness. This cyclical process is activated when patients perceive a discrepancy between their current health state and a desired goal state, motivating behavioral adjustment.

Leventhal's Common-Sense Model of Self-Regulation (CSM), also known as the Illness Perception Model, extends this framework by elucidating how patients construct cognitive and emotional representations of their illness and how these representations drive coping behaviors (Leventhal et al., 2012). The CSM proposes five illness representation dimensions: identity (symptom recognition), cause attribution, timeline perception, consequence evaluation, and controllability beliefs. These representations operate in parallel with emotional representations (fear, anxiety, distress) to shape self-regulatory behaviors. Empirical validation of the CSM in T2DM populations has demonstrated that accurate illness representations and low emotional distress are associated with higher adherence to dietary, physical activity, and medication regimens (Fall & others, 2021).

In the specific context of T2DM, self-regulation encompasses five behavioral domains: (1) physical activity a minimum of 150 minutes of moderate-intensity aerobic exercise per week as recommended by clinical guidelines; (2) dietary control structured meal planning with appropriate carbohydrate, protein, and fat distribution and regular meal timing; (3) blood glucose monitoring and medication adherence routine glucometric surveillance and compliance with pharmacological regimens; (4) health service utilization consistent attendance at scheduled consultations and diabetes education programs; and (5) stress management application of psychological coping strategies to minimize cortisol-mediated insulin resistance (Carver & Scheier, 2016; Ryan & Deci, 2000). Patients who achieve strong self-regulation across all five domains demonstrate significantly superior glycemic control and report higher health-related QoL compared to those with low self-regulation (Fadli & others, 2024).

2.3. Family-Centered Nursing

Family-Centered Nursing (FCN) is a philosophical and practical framework in which the family is conceptualized not as a contextual backdrop, but as the primary unit of care (Friedman et al., 2003). FCN recognizes that health and illness occur within family systems, and that the family's structure, function, stress level, coping capacity, and knowledge directly influence the health outcomes of its members. Friedman's FCN model delineates comprehensive assessment domains encompassing sociocultural data, environmental factors, family structure and function (affective, socialization, healthcare, reproductive, and economic functions), family stress using the Perceived Stress Scale (PSS), strategic coping mechanisms, and family knowledge. These domains collectively capture the multidimensional ways in which family dynamics interact with individual health behaviors.

Family support, operationalized within the FCN framework, comprises four functional dimensions: informational support (provision of disease management information), emotional

support (expression of empathy, reassurance, and encouragement), instrumental support (tangible practical assistance such as meal preparation, medication reminding, and transportation to clinical appointments), and appraisal support (constructive feedback and recognition of patient effort) (Friedman et al., 2003). Multiple meta-analyses and systematic reviews have confirmed that high-quality family support across these four dimensions is robustly associated with improved diabetes self-management adherence, better glycemic outcomes, lower rates of diabetes-related distress, and higher QoL (Browne & others, 2022; Pamungkas et al., 2017). The FCN framework thus provides both the theoretical architecture and the practical assessment tools required to integrate family engagement into structured diabetes interventions.

In the Indonesian sociocultural context, where extended family systems and collectivist values characterize domestic life, FCN principles are particularly culturally resonant. Family members in Indonesian households are typically deeply invested in the health management of chronically ill relatives, yet often lack the knowledge, skills, and structured guidance necessary to translate this investment into effective supportive behaviors. This gap between motivation and capacity constitutes a critical intervention point that the FCN-EL model directly addresses by equipping both patients and family members with practical competencies through the experiential learning structure.

2.4. Kolb's Experiential Learning Theory

Kolb's Experiential Learning Theory (ELT) postulates that the deepest and most durable learning occurs through a four-stage cyclical process that integrates experience, reflection, conceptualization, and application (Kolb, 2015). The four stages are: Concrete Experience (CE) immersion in a real, specific experience; Reflective Observation (RO) deliberate contemplation of the experience from multiple perspectives; Abstract Conceptualization (AC) synthesis of reflections into generalizable principles and theories; and Active Experimentation (AE) testing of new concepts in novel situations to generate further concrete experience. This cycle is self-reinforcing: each completed revolution produces more sophisticated experience and increasingly nuanced understanding.

Applied to T2DM self-management education, ELT offers several critical advantages over didactic instruction. First, it grounds learning in the patient's own lived experience of managing diabetes, making educational content immediately relevant and personally meaningful. Second, the structured reflective phase encourages metacognitive awareness, enabling patients to identify personal barriers to self-care adherence that might not emerge through passive information reception. Third, the conceptualization phase ensures that experiential insights are integrated with evidence-based principles, preventing the consolidation of maladaptive beliefs or practices. Fourth, the active experimentation phase closes the knowing-doing gap by supporting real-world behavioral practice in authentic daily contexts, with family members serving as social partners in the experimental process (Cheng & others, 2024; Ibrahim & others, 2024).

Several empirical studies have documented the effectiveness of ELT-based interventions in T2DM. Wang et al. (2022) demonstrated that small-group experiential learning programs significantly improved blood glucose regulation and health-promoting behaviors in elderly T2DM patients compared to conventional instruction. Cheng et al. (2024) reported that an eHealth experiential learning program significantly improved eHealth literacy, patient engagement, and self-management utilization in T2DM populations. Munson et al. (2023) explored the integration of experiential learning with dietary behavior change in diabetes prevention programs, identifying access and experiential engagement as key facilitators of dietary improvement. These findings collectively support the proposition that ELT provides a pedagogical framework uniquely suited to the complex, multidimensional, and sustained behavioral demands of T2DM self-management.

2.5. Quality of Life

Quality of life in T2DM is conceptualized as a multidimensional construct encompassing physical health, psychological well-being, social relationships, and environmental conditions (World Health Organization, 1997). The Diabetes Quality of Life (DQOL) instrument, developed by Jacobson et al. and adapted for the Indonesian context by Tyas (2008), operationalizes QoL through four dimensions: patient satisfaction with treatment, disease impact on daily function, social and vocational concerns, and worry about future diabetes-related effects (Thiagarajan, 1998). Research consistently documents poor QoL in T2DM populations globally, with particularly pronounced deficits in physical health and psychological domains as disease duration and complication burden increase (Chaidir & others, 2017; Zare & others, 2020).

Glycemic control, indexed by fasting plasma glucose and HbA1c levels, is both a determinant and a consequence of QoL in T2DM. Adequate glycemic control reduces the risk of microvascular and macrovascular complications, thereby preserving physical function and psychological well-being. Conversely, poor glycemic control generates complications that impair mobility, cause pain, and create psychological burden, all of which degrade QoL. The bidirectional relationship between glycemic control and psychological well-being is mediated by several mechanisms: depression and anxiety associated with poor QoL directly impair self-care adherence through motivational deficits and cognitive interference; elevated cortisol from chronic psychological stress induces insulin resistance; and reduced physical function from complications diminishes the patient's capacity to engage in exercise and dietary self-management (Fall & others, 2021; Magliah & others, 2021). Targeting self-regulation behaviors that simultaneously improve glycemic control and psychological well-being is therefore a theoretically and clinically coherent strategy for QoL enhancement in T2DM.

3. METHODS

3.1. Research Design

This study employed a three-phase explanatory research design. Phase 1 used a quantitative cross-sectional approach to identify and quantify the structural determinants of self-regulation and quality of life in T2DM patients. Phase 2 involved the systematic participatory development of a structured self-regulation intervention module. Phase 3 (ongoing) will evaluate module effectiveness through a quasi-experimental Pre-Post Test Control Group Design. Ethical clearance was granted by the Research Ethics Committee of ITEKES Muhammadiyah Kalimantan Barat (No. 125/II.I.AU/KET.ETIK/X/2025). All participants provided written informed consent prior to data collection.

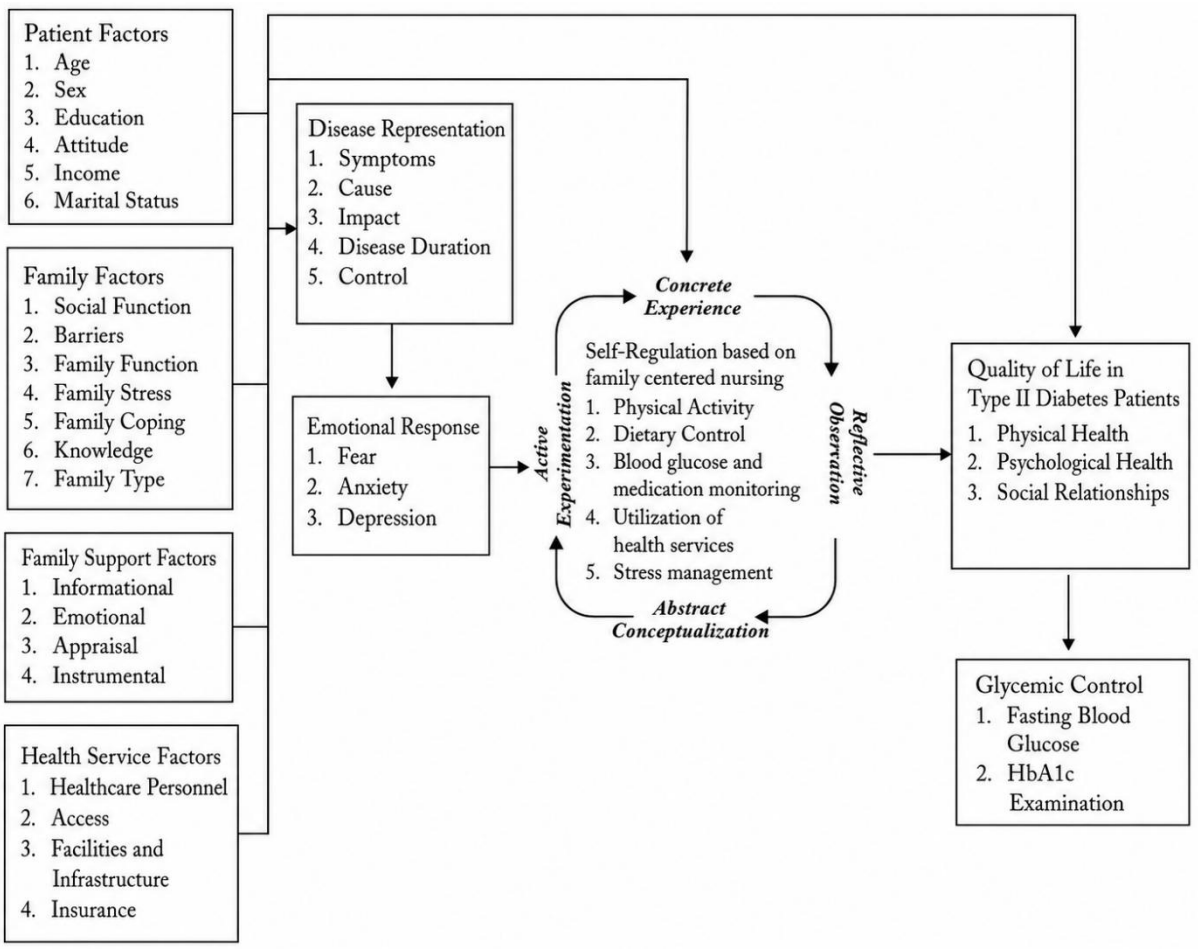

Figure 1. Concept Framework

3.2. Phase 1: Cross-Sectional Quantitative Study

3.2.1. Setting, Population, and Sampling

The study was conducted in community health centers (puskesmas) under the jurisdiction of the Pontianak City Health Office, West Kalimantan, Indonesia. The target population comprised all registered T2DM patients in Pontianak City (N = 3,085). Sample size was determined using the rule-of-thumb criterion of five observations per estimated model parameter (Patton, 2001); with 31 parameters in the theoretical model, a minimum sample of 155 was required. Multistage random sampling was applied: in Stage 1, four of six administrative subdistricts (kecamatan) were randomly selected; in Stage 2, 10 of 23 puskesmas were randomly selected from the sampled subdistricts; in Stage 3, individual patients were recruited via simple random sampling from patient registries at each selected puskesmas. Inclusion criteria required: confirmed T2DM diagnosis for at least 12 months; age 36–65 years; and ability to cooperate during data collection. Exclusion criteria were: presence of serious comorbid complications requiring specialized care; and cognitive or psychiatric impairment precluding questionnaire completion.

3.2.2. Measurement Instruments

Data were collected using eight self-administered, validated questionnaires. (1) Patient Factor Questionnaire: Demographic characteristics (age, sex, education, income, marital status) and the Diabetes Attitude Survey (16 items, Likert 1–4) for attitude assessment. (2) Family Factor Questionnaire: Incorporates the modified APGAR Family Questionnaire (10 items) for social function; a Family Barrier Questionnaire (8 items); a Family Function Questionnaire (10 items); the Perceived Stress Scale (PSS-10); a Coping Inventory based on Folkman et al. (15 items); a Family Knowledge Questionnaire (23 items); and a Family Type classification (7

categories). (3) Hensarling Diabetes Family Support Scale (HDFSS): 25 items across four dimensions (informational, emotional, appraisal, and instrumental support; Likert 1–4). (4) Health Service Quality Questionnaire: Covers healthcare worker quality (10 items), access (7 items), infrastructure (10 items), and insurance utilization (2 items). (5) Illness Perception Questionnaire (IPQ): Adapted from the original IPQ, 11 items covering symptom identity, causal attribution, disease impact, timeline, and controllability. (6) Emotional Response Questionnaire: 10 items measuring fear, anxiety, and depression based on Ogden's (2007) model. (7) Self-Regulation Questionnaire: 53 items across five sub-domains (physical activity, dietary control, blood glucose and medication monitoring, health service utilization, and stress management; Likert 1–4). (8) Diabetes Quality of Life (DQOL) Questionnaire: 30 items assessing physical, psychological, and social health domains.

All instruments were piloted on 30 T2DM patients and family members at two puskesmas not included in the main study (Puskesmas Paris 2 and Puskesmas Parit Mayor, 9–15 August 2025). Validity testing used Pearson correlation, with all items achieving $r > 0.361$ ($n = 30$, significance level 5%). Reliability was assessed using Cronbach's alpha, with all subscales demonstrating $\alpha \geq 0.794$. The full validation results are presented in the supplementary material.

3.2.3. Statistical Analysis

Descriptive statistics included frequency distributions, means, and standard deviations. Inferential analysis employed SEM-PLS using SmartPLS version 4.0. The outer model was evaluated for: (a) convergent validity through outer loading coefficients (threshold ≥ 0.50, with ≥ 0.70 preferred); (b) discriminant validity using the Heterotrait-Monotrait (HTMT) ratio (< 0.90) and comparison of the square root of Average Variance Extracted (AVE) against inter-construct correlations (Fornell-Larcker criterion); and (c) construct reliability using Cronbach's alpha and Composite Reliability (both > 0.70) and AVE (> 0.50). The inner model was evaluated through: R^2 values categorized as strong (≥ 0.75), moderate (0.50–0.74), or weak (0.25–0.49) (Chin, 1998); predictive relevance (Q^2) via blindfolding ($Q^2 > 0$ indicates predictive validity); and path coefficient significance via bootstrapping with 5,000 subsamples (t-statistic > 1.96, two-tailed, $p < 0.05$).

3.3. Phase 2: Module Development

Phase 2 comprised four sequential steps: strategic issue identification, focus group discussions, expert consultation, and content validity assessment. Strategic issues were operationally defined as variables or sub-domains meeting all three of the following criteria: (a) a problematic response rate of ≥ 20% in Phase 1 descriptive analysis; (b) a statistically significant pathway in the SEM-PLS structural model ($p < 0.05$); and (c) theoretical and practical relevance supported by peer-reviewed literature.

Two FGDs were conducted. FGD 1 (29 November 2025, Puskesmas Alianyang; n = 20 T2DM patients and family representatives; 90 minutes) explored patients' experiential perspectives on self-management barriers, family involvement, emotional responses to disease, and unmet informational needs, guided by the seven identified strategic issues. FGD 2 (13 December 2025, online platform; n = 20 PROLANIS nurses; 90 minutes) elicited nurses' professional assessments of barriers to effective diabetes education, current care gaps, and recommendations for module content, format, and delivery methods. Both FGDs were audio-recorded with participant consent, transcribed verbatim, and subjected to thematic content analysis using inductive category formation.

Expert consultation was conducted with five specialists: (1) an internist and endocrinologist/metabolic disease consultant (Sp.PD-KEMD, FINASIM); (2) a professor of medical-surgical nursing with specialization in T2DM management (MSN, AWCS); (3) a certified diabetes nurse educator (S.Kep, Ns); and (4–5) two PROLANIS nurse practitioners (S.Kep, Ns; one with additional M.Kep qualification). Experts reviewed the draft module and provided written recommendations regarding clinical accuracy, pedagogical design, language

accessibility, visual presentation, and practical implementability. The module was revised iteratively based on expert feedback before proceeding to content validity assessment.
Content validity was assessed by the same five experts using a four-point CVI rating scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant) across five domains: content appropriateness, technical presentation, language quality, graphical design, and suitability as a health promotion medium. Item-level CVI (I-CVI) was calculated as the proportion of experts rating an item 3 or 4, and Scale-level CVI (S-CVI/Ave) was computed as the mean I-CVI across all items. An I-CVI ≥ 0.78 and S-CVI/Ave ≥ 0.90 were considered acceptable thresholds (Polit & Beck, 2006).

4. RESULTS

4.1. Phase 1 Results

4.1.1. Participant Characteristics

The final sample comprised 155 T2DM patients. The demographic profile is presented in Table 1. The majority of participants were in the 46–55-year age group (50.3%), female (79.4%), and had attained senior secondary education (38.1%). The preponderance of female participants reflects the higher healthcare-seeking behavior of women and the higher age-adjusted prevalence of T2DM among women in the Indonesian setting. Most participants demonstrated a positive attitude toward disease management (96.1%), consistent with the sociocultural norm of stoic acceptance of chronic illness in this population. Economic vulnerability was prevalent, with 56.8% of participants earning below the regional minimum wage (IDR 1,975,000/month). Marital status showed that 87.7% of participants were currently married, ensuring a relevant family support context. Duration of T2DM was predominantly 1–5 years (67.7%), suggesting a sample still in the early-to-middle phase of disease management.

Table 1. Sociodemographic characteristics of study participants (n = 155)

Variable	Category	n	%
Age (years)	36–45	30	19.4
	46–55	78	50.3
	56–65	47	30.4
Sex	Male	32	20.6
	Female	123	79.4
Education	No schooling / Primary	47	30.3
	Junior secondary	29	18.7
	Senior secondary	59	38.1
	Higher education	20	12.9
Attitude toward management	Positive	149	96.1
	Negative	6	3.9
Monthly income (IDR)	< 1,975,000	88	56.8
	1,975,000 – 3,500,000	46	29.7
	> 3,500,000	21	13.5
Marital status	Married	136	87.7

	Widow/er	17	11.0
	Single	2	1.3
T2DM duration (years)	1–5	105	67.7
	5–10	28	18.1
	> 10	22	14.2

4.1.2. Descriptive Analysis of Primary Variables

Among family factors, 91.6% of patients reported good family social function, while 67.7% experienced moderate family barriers to supportive caregiving. Family stress was predominantly at a moderate level (67.1%), with adequate family coping (85.2%) and good family knowledge of diabetes management (86.5%). For family support, high levels were reported across all four dimensions: informational (94.2%), emotional (88.4%), appraisal (94.2%), and instrumental (91.6%), indicating that most families were engaged and supportive. Regarding disease representation, the majority of patients perceived disease impact as moderate (93.5%), while controllability beliefs were evenly distributed between good (48.4%) and moderate (47.1%). For emotional response, 61.9% of patients reported moderate anxiety and 83.2% reported mild depression, with 22.6% reporting severe fear of disease complications. These data confirm a high prevalence of subclinical psychological distress in the study population.

Self-regulation profiles revealed that blood glucose and medication monitoring was the strongest domain (75.5% rated good), while stress management was the most deficient (only 45.2% good, and 23.2% poor). This stress management deficit is clinically significant given the established pathway from psychological stress to cortisol-mediated insulin resistance. Quality of life was generally favourable in this sample: physical health (81.3% good), psychological health (96.1% good), and social relationships (90.3% good).

Table 2. Descriptive distribution of self-regulation sub-domain scores (n = 155)

Self-Regulation Sub-domain	Good (%)	Adequate (%)	Poor (%)
Physical activity	56.1	37.4	6.5
Dietary control	58.1	31.0	11.0
Blood glucose & medication monitoring	75.5	18.7	5.8
Health service utilization	65.2	23.9	11.0
Stress management	45.2	31.6	23.2

4.1.3. Measurement Model (Outer Model) Evaluation

Initial model estimation identified five indicators with outer loadings below the acceptable threshold of 0.50: Age (0.237), Sex (0.358), Family Social Function (0.352), Family Type (0.403), and Insurance (0.275). The low loading of Age and Sex as indicators of the Patient Factors construct likely reflects their weak direct association with self-regulation once attitudinal, educational, and economic factors are controlled. The low loadings of Family Social Function and Family Type may indicate that these structural dimensions of family organization are less directly predictive of diabetes-specific outcomes compared to functional dimensions such as coping and knowledge. Insurance loading was low possibly because most patients were insured and utilized their coverage (84.5%), producing insufficient variance to discriminate

responses. These five indicators were eliminated, and the model was re-estimated with the remaining indicators.

Following elimination, all remaining indicators achieved outer loadings ranging from 0.762 to 0.942, well above the 0.70 threshold. Discriminant validity was confirmed: HTMT ratios were below 0.90 for all construct pairs, and the square root of each construct's AVE exceeded its highest inter-construct correlation. All constructs demonstrated strong internal consistency (Cronbach's alpha: 0.767–0.935) and acceptable convergent validity (AVE: 0.556–0.837), as detailed in Table 3.

Table 3. Construct reliability and validity statistics for the final measurement model

Construct	Cronbach's α	Composite Reliability	AVE	Interpretation
Patient Factors (X1)	0.804	0.866	0.556	Reliable & Valid
Family Factors (X2)	0.859	0.901	0.586	Reliable & Valid
Family Support (X3)	0.935	0.954	0.837	Highly Reliable & Valid
Health Services (X4)	0.767	0.847	0.610	Reliable & Valid
Disease Representation (X5)	0.930	0.947	0.781	Highly Reliable & Valid
Emotional Response (X6)	0.891	0.933	0.822	Highly Reliable & Valid
Self-Regulation (X7)	0.935	0.950	0.793	Highly Reliable & Valid
Quality of Life (Y1)	0.799	0.869	0.624	Reliable & Valid

4.1.4. Structural Model (Inner Model) and Hypothesis Testing

The structural model demonstrated strong predictive capacity: $R^2 = 0.867$ for self-regulation, indicating that patient factors, family factors, family support, health service quality, and emotional response collectively explained 86.7% of variance in self-regulation; and $R^2 = 0.807$ for quality of life, indicating that patient factors, family factors, family support, health services, and self-regulation explained 80.7% of QoL variance. By contrast, disease representation ($R^2 = 0.247$) and emotional response ($R^2 = 0.218$) yielded weak R^2 values, confirming that these constructs are substantially influenced by factors outside the present model, including personality traits, cultural beliefs, and health literacy not captured by the current instruments. Predictive relevance was confirmed for both endogenous constructs: $Q^2 = 0.524$ for self-regulation and $Q^2 = 0.572$ for quality of life, both substantially above zero.

The full hypothesis testing results are presented in Table 4. Among the direct pathways, family support exerted the strongest direct effect on quality of life ($\beta = 0.331$, $t = 6.711$), followed by patient factors ($\beta = 0.272$, $t = 4.864$), family factors ($\beta = 0.252$, $t = 5.524$), and health services ($\beta = 0.132$, $t = 3.202$). For self-regulation, patient factors were the strongest predictor ($\beta = 0.469$, $t = 10.355$), followed by family support ($\beta = 0.412$, $t = 10.696$), family factors ($\beta = 0.331$, $t = 8.754$), and health services ($\beta = 0.189$, $t = 5.790$). Notably, only patient factors significantly predicted disease representation ($\beta = 0.486$, $t = 8.563$); family factors, family support, and health services did not reach significance for this pathway (all $p > 0.05$). Disease representation significantly predicted emotional response ($\beta = 0.467$, $t = 7.464$), emotional response significantly predicted self-regulation ($\beta = 0.465$, $t = 12.958$), and self-regulation

significantly predicted quality of life (β = 0.435, t = 6.812). All reported pathways were significant at $p < 0.001$ unless otherwise noted.

Table 4. Structural model hypothesis testing results (bootstrapping n = 5,000)

Pathway	β	t-Stat	p-Value	Decision
Patient Factors (X1) → Quality of Life (Y1)	0.272	4.864	< 0.001	Supported
Family Factors (X2) → Quality of Life (Y1)	0.252	5.524	< 0.001	Supported
Family Support (X3) → Quality of Life (Y1)	0.331	6.711	< 0.001	Supported
Health Services (X4) → Quality of Life (Y1)	0.132	3.202	0.001	Supported
Patient Factors (X1) → Self-Regulation (X7)	0.469	10.355	< 0.001	Supported
Family Factors (X2) → Self-Regulation (X7)	0.331	8.754	< 0.001	Supported
Family Support (X3) → Self-Regulation (X7)	0.412	10.696	< 0.001	Supported
Health Services (X4) → Self-Regulation (X7)	0.189	5.790	< 0.001	Supported
Patient Factors (X1) → Disease Representation (X5)	0.486	8.563	< 0.001	Supported
Family Factors (X2) → Disease Representation (X5)	0.013	0.164	0.870	Not Supported
Family Support (X3) → Disease Representation (X5)	0.079	1.056	0.291	Not Supported
Health Services (X4) → Disease Representation (X5)	-0.109	1.477	0.140	Not Supported
Disease Representation (X5) → Emotional Response (X6)	0.467	7.464	< 0.001	Supported
Emotional Response (X6) → Self-Regulation (X7)	0.465	12.958	< 0.001	Supported
Self-Regulation (X7) → Quality of Life (Y1)	0.435	6.812	< 0.001	Supported

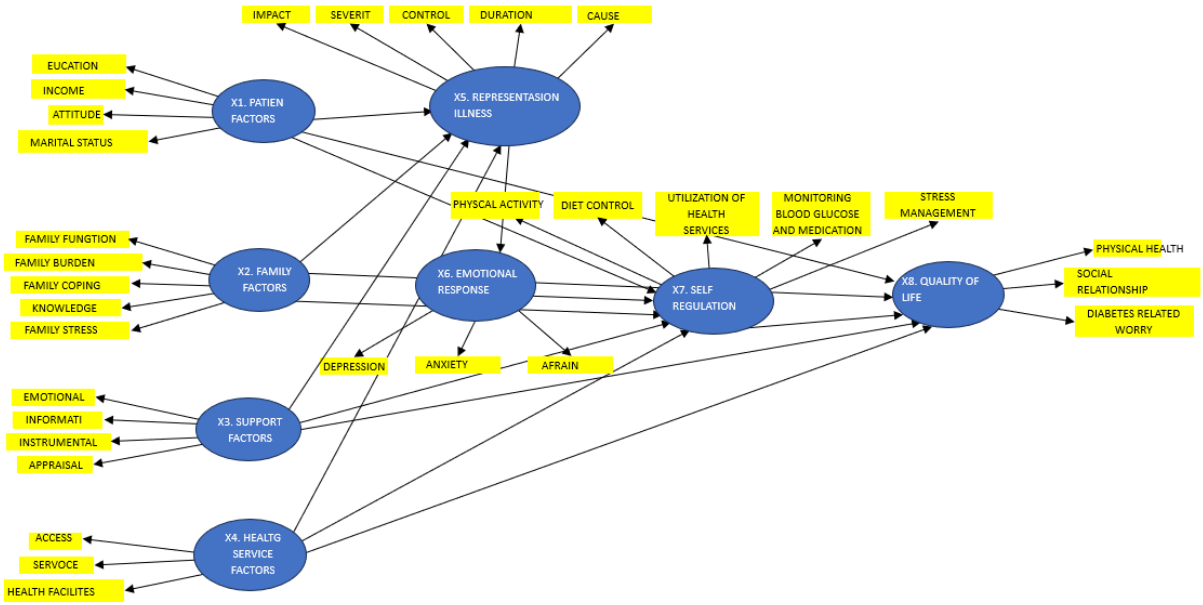

Figure 2. Final SEM-PLS path diagram of the FCN-EL self-regulation model

4.2. Phase 2 Results: Module Development

4.2.1. Strategic Issues and FGD Findings

Seven strategic issues were identified from Phase 1 results and confirmed through FGD triangulation: (1) low education and income as barriers to optimal disease management; (2) family knowledge gaps and moderate-to-severe family barriers limiting supportive caregiving; (3) suboptimal emotional and instrumental family support in daily diabetes practice; (4) limited patient understanding of disease mechanisms, symptom attribution, and self-management rationale; (5) moderate-to-high anxiety and mild depression as prevalent emotional responses impeding self-regulation; (6) fluctuating self-regulation across all five behavioral domains, with stress management as the most deficient; and (7) suboptimal overall quality of life, particularly in the physical health domain.

FGD 1 (patients) generated seven thematic clusters: knowledge deficiency about diabetes beyond basic medication use; passive attitudes toward disease management driven by the belief that hyperglycemia is asymptomatic; financial constraints limiting dietary modification and regular monitoring; emotional burden including fear of complications and progressive dependency; family support perceived as important but practically inconsistent; limited access to culturally appropriate, literacy-friendly educational materials; and desire for practical, skills-based learning opportunities rather than lecture-format education. These themes directly informed the module's emphasis on practical demonstrations, visual materials, family role operationalization, and accessible language.

FGD 2 (PROLANIS nurses) yielded complementary themes: absence of structured family-inclusive educational tools within the PROLANIS program; inconsistency in the depth and frequency of patient counseling due to consultation time constraints; nurses' observed correlation between low family engagement and poor glycemic control among their patients; strong endorsement of a module incorporating experiential demonstration components, case-based role plays, and follow-up monitoring schedules; and recommendations for module design emphasizing colored visual summaries, concise chapter learning objectives, and formative self-assessment tools at each stage.

4.2.2. Expert Consultation Outcomes

Expert consultation produced five key recommendations that were fully incorporated into the final module: (1) the endocrinologist recommended limiting each chapter to clinically essential content, supplemented by illustrative diagrams, to avoid cognitive overload in patients with limited health literacy; (2) the nursing professor recommended translating family roles into

specific, observable behavioral indicators (e.g., "family member checks patient's blood glucose log three times per week" rather than "family supports monitoring"), ensuring that the module is actionable rather than conceptual; (3) the diabetes nurse educator emphasized the need for culturally empathetic language and recommended incorporating local dietary examples for the meal planning sections; (4–5) both PROLANIS nurses independently recommended the inclusion of structured learning objectives at each session and Likert-scale self-assessment tools for patients to monitor behavioral progress between sessions.

4.2.3. Module Description and Structure

The finalized FCN-EL Self-Regulation Module for T2DM Patients is structured around Kolb's four experiential learning stages, delivered across a 12-week implementation period comprising 11 group sessions and individual home practice between sessions. The module contains six content chapters: Chapter 1 Diabetes Mellitus: Definition, Etiology, Pathophysiology, and Complications; Chapter 2 Evidence-Based Diabetes Management (the 5J principle: physical activity, diet, blood glucose and medication monitoring, health service utilization, and stress management); Chapter 3 Self-Regulation in T2DM: Principles, Components, and Barriers; Chapter 4 Family Role in T2DM Self-Regulation: FCN Framework and Family Support Operationalization; Chapter 5 FCN-EL Practice: Integrated Sessions Across the Four Experiential Learning Stages; Chapter 6 Quality of Life in T2DM: Domains, Determinants, and Self-Monitoring.

The Concrete Experience phase (Weeks 1–2; 2 sessions × 90 minutes) uses structured narrative sharing, brainstorming, and peer testimonials to elicit patients' and family members' existing knowledge and experiential understanding of diabetes management across all five behavioral domains. The Reflective Observation phase (Weeks 3–4; 2 sessions × 90 minutes) guides patients through structured reflection on their self-management experiences using facilitated group discussion and personal reflection worksheets, identifying facilitating and hindering factors for each domain. The Abstract Conceptualization phase (Weeks 5–8; 4 sessions × 60 minutes) introduces evidence-based self-management principles through interactive lectures, case studies, and role-play simulations, enabling patients to formulate personalized self-regulation plans that integrate family roles. The Active Experimentation phase (Weeks 9–12; 4 sessions × 60 minutes plus daily home practice) supports real-world implementation of individualized plans, with family members as active behavioral partners, monitored through structured self-report logs and reviewed at each weekly session. The module concludes with a post-evaluation session including assessment of HbA1c, fasting blood glucose, and DQOL scoring.

Table 5. Content Validity Index (CVI) results for the FCN-EL module (n = 5 expert reviewers)

Validity Domain	CVI (S-CVI/Ave)	Reliability (%)
Content appropriateness	1.00	100
Technical presentation quality	1.00	100
Language quality and accessibility	1.00	100
Graphical and layout design	1.00	100
Suitability as a health promotion medium	1.00	100
Overall	1.00	100

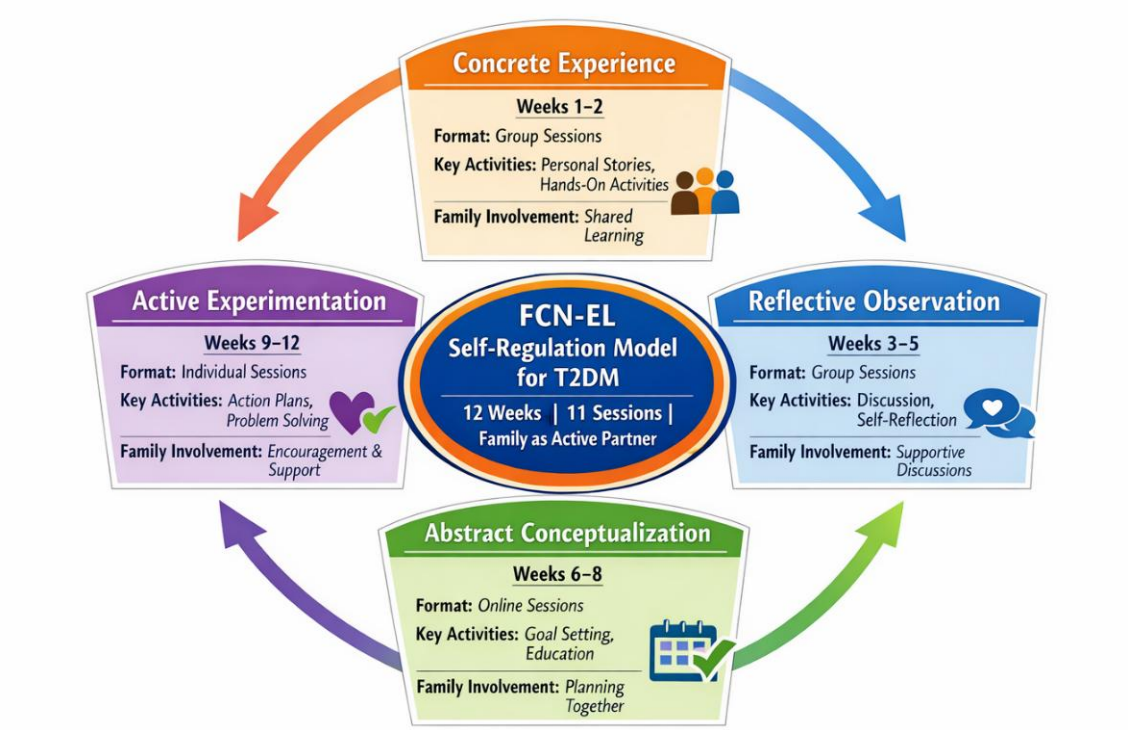

Figure 3. Schematic overview of the FCN-EL module delivery structure

5. DISCUSSION

5.1. Structural Determinants of Quality of Life: A Multi-Level Analysis

The SEM-PLS structural model confirmed that quality of life in T2DM is a multi-determined outcome shaped by individual, family, relational, and systemic factors, together explaining 80.7% of its variance. Among direct predictors, family support emerged as the strongest (β = 0.331), followed by patient factors (β = 0.272), family factors (β = 0.252), and health service quality (β = 0.132). The primacy of family support over individual patient characteristics in directly predicting QoL is theoretically important, as it empirically validates the FCN premise that quality of life in chronic illness is fundamentally a relational rather than purely individual outcome (Friedman et al., 2003). This finding is consistent with Browne et al.'s (2022) meta-analytic conclusion that social support is a robust predictor of QoL in T2DM, and extends it by demonstrating that family support's influence on QoL is partially direct and partially mediated through self-regulation capacity.

The individual patient characteristics that most powerfully predicted both QoL and self-regulation were attitude, education, and income. Attitude was the strongest indicator within the Patient Factors construct, corroborating self-determination theory's postulation that autonomous motivation and positive health valuation are prerequisites for sustained behavioral engagement (Ryan & Deci, 2000). Patients with positive attitudes toward their disease interpret management demands as personally meaningful rather than externally imposed, producing higher intrinsic motivation for self-care adherence. The influence of education and income on QoL reflects the compounding disadvantages of structural socioeconomic vulnerability: low health literacy constrains patients' ability to understand, evaluate, and apply self-management information, while financial hardship restricts access to the dietary, pharmacological, and recreational resources that support physical and psychological well-being (Saeedi et al., 2019). Health service quality, while having the smallest direct path coefficient (β = 0.132), nevertheless constituted a statistically and practically significant determinant of QoL, acting through both its direct effect and its stronger indirect effect via self-regulation enhancement (β = 0.189). This finding underscores the irreplaceable role of healthcare infrastructure and professional competence in enabling effective self-management. Patients who receive consistent, high-quality care from knowledgeable and empathetic healthcare workers develop

stronger self-efficacy, better disease understanding, and more robust self-regulation behaviors compared to those receiving poor quality care. The elimination of insurance utilization as a valid indicator in the final model suggests that passive insurance ownership does not independently contribute to QoL beyond the quality-of-care access it enables, a distinction carrying important implications for health financing policy.

5.2. The Sequential Mediation Pathway: A Theoretical Contribution

One of the most theoretically significant findings of this study is the empirical confirmation of a sequential mediation pathway from disease representation through emotional response to self-regulation and ultimately to quality of life. This pathway, which operates independently of and alongside the direct effects of the four exogenous constructs, constitutes a novel empirical contribution to the T2DM self-management literature.

The finding that patient factors exclusively predicted disease representation ($\beta = 0.486$), while family factors, family support, and health service quality did not, aligns with Leventhal et al.'s (2012) original theorization of illness representations as primarily personal cognitive constructions shaped by individual health beliefs, education, and experiential history rather than external social or systemic inputs. This implies that illness misrepresentations, such as the belief that diabetes is a purely pharmacological condition requiring no behavioral modification, are deeply rooted in individual cognitive schemas that are not easily dislodged by family conversations or clinic encounters alone. Targeted, individually tailored psychoeducational interventions addressing these misrepresentations are therefore essential, which is precisely what the Abstract Conceptualization phase of the FCN-EL module provides.

Disease representation predicting emotional response ($\beta = 0.467$) confirms Ogden's (2007) theoretical framework, which posits that the perceived threat level of a health condition, as constructed through illness representations, directly generates a corresponding emotional response. Patients who perceive their diabetes as highly threatening (severe consequences, long timeline, low controllability) generate higher levels of fear, anxiety, and depression than those with more adaptive, accurate representations. The magnitude of this path coefficient, combined with the strong predictive effect of emotional response on self-regulation ($\beta = 0.465$, highest t-value in the model at 12.958), confirms that unmanaged emotional distress is the primary mechanism through which cognitive illness representations translate into behavioral disengagement from self-care. This finding has direct clinical implications: it argues for the systematic integration of validated psychological screening instruments (such as the Diabetes Distress Scale and GAD-7) into routine T2DM management protocols, followed by targeted emotional regulation interventions for patients scoring above clinical thresholds.

5.3. Self-Regulation as the Central Behavioral Mediator

The model's R^2 of 0.867 for self-regulation demonstrates that the combined determinants in the model explain nearly all variance in self-regulation that can be attributed to measured factors. This robust explanatory power validates the theoretical comprehensiveness of the FCN-EL model framework and suggests that the five identified determinant domains (patient characteristics, family context, family support, health service access, and emotional regulation) collectively capture the most critical influences on self-regulation in this population.

Among the determinants, family support's strong direct effect on self-regulation ($\beta = 0.412$, $t = 10.696$) deserves particular emphasis. This finding confirms that family support is not merely a background facilitator but a constitutive component of effective self-regulation in T2DM, operating through multiple mechanisms. Informational support provides the cognitive resources (disease knowledge and management skills) necessary for competent self-care decision-making. Emotional support provides the motivational fuel and psychological stability that sustain behavioral engagement through setbacks and disease fluctuations. Instrumental support reduces the practical burden of self-care by distributing management responsibilities across household members. Appraisal support reinforces behavioral progress through positive feedback, activating reinforcement learning mechanisms that consolidate adaptive health behaviors over time (Browne & others, 2022; Gonzalez & others, 2016).

The stress management domain's status as the most deficient self-regulation sub-domain (45.2% good; 23.2% poor) is a clinically significant finding that demands targeted intervention. Diabetes-related distress encompasses three primary sources: burden of self-care demands, fear of hypoglycemia and complications, and relational burden of diabetes on family dynamics (Magliah & others, 2021). The FCN-EL module addresses all three sources: the Active Experimentation phase introduces evidence-based stress management techniques (mindfulness-based relaxation, diaphragmatic breathing, cognitive reframing) and supports patients in practicing these under the guidance of family members who serve as coping partners. This family-mediated stress management strategy is consistent with social support theory's proposition that emotional regulation is most effective when embedded within supportive interpersonal relationships (Miles & others, 2018).

5.4. Module Development, Validity, and Practical Implementation

The FCN-EL module achieved perfect content validity (CVI = 1.00) across all five evaluation domains, surpassing the established acceptability threshold of 0.80 ((Polit & Beck, 2006). This universal expert agreement reflects the module's strong theoretical grounding, clinical accuracy, and contextual relevance to the target population. The participatory development process, which integrated quantitative Phase 1 evidence with qualitative FGD insights from both patients and nurses, and iterative expert review, exemplifies best practices in health education material development as recommended in the health promotion literature.

The module's alignment with Kolb's four experiential learning stages provides a pedagogically sound structure that addresses the critical limitations of conventional diabetes education. Where traditional DSMES programs transfer information didactically without connecting it to personal experience, the Concrete Experience phase activates patients' existing experiential knowledge as the entry point for learning. Where traditional programs focus on the "what" of self-management without addressing the "why" or the barriers, the Reflective Observation phase creates structured space for metacognitive processing of personal self-management experiences. Where traditional programs present generic guidelines that patients cannot contextually translate into their daily lives, the Abstract Conceptualization phase co-constructs individualized management plans with each patient's unique household and lifestyle context as the reference frame. Where traditional programs provide knowledge without practice support, the Active Experimentation phase closes the knowing-doing gap through supervised real-world behavioral implementation with family co-participants.

From a nursing practice perspective, the FCN-EL module operationalizes FCN principles in a concrete, reproducible, and contextually sensitive manner that extends beyond the conceptual level of existing family nursing frameworks. By translating "family support" from an abstract theoretical dimension into specific, observable, schedulable behaviors such as a family member reviewing the patient's blood glucose log three times weekly, or accompanying the patient on prescribed walks the module makes family engagement practically implementable and evaluable. This operationalization is one of the module's most distinctive and practically valuable contributions, as it addresses the frequent gap between families' intention to support and their ability to do so effectively without structured guidance.

5.5. Limitations and Future Directions

Several limitations of this study warrant acknowledgement. The Phase 1 cross-sectional design precludes causal inference; while SEM-PLS identifies structural relationships congruent with the theoretical model, longitudinal evidence is required to confirm temporal directionality. The single urban Indonesian setting may limit generalizability to rural areas, remote communities, or culturally distinct populations with different family structures and healthcare access profiles. Self-reported measurement of self-regulation behaviors is susceptible to social desirability bias and recall inaccuracy, potentially inflating adherence estimates. The five-expert content validity sample, while meeting standard recommendations, represents a relatively small validation panel; larger multi-institutional expert panels and target population pilot testing would strengthen the validity evidence. Finally, Phase 3 data on the clinical effectiveness of

the FCN-EL module on QoL and glycemic outcomes (HbA1c and fasting blood glucose) are currently being collected and will be reported in a subsequent publication.
Future research should address these limitations through: (a) longitudinal quasi-experimental or randomized controlled trial designs with adequate follow-up periods to assess sustained behavioral and clinical outcomes; (b) multi-site sampling across urban and rural Indonesian settings to assess generalizability; (c) objective measurement of physical activity using accelerometry and dietary intake using food frequency instruments to supplement self-report data; (d) adaptation and cultural validation of the FCN-EL module for implementation in settings with different sociocultural norms around family involvement in healthcare; (e) health economic analysis of the FCN-EL intervention to assess cost-effectiveness relative to standard PROLANIS care; and (f) exploration of digital delivery platforms (mobile applications, telehealth) to extend module reach in geographically dispersed populations.

6. CONCLUSION

This study developed and validated a comprehensive self-regulation model based on Family-Centered Nursing and Experiential Learning Theory for improving quality of life and glycemic control in T2DM patients. Phase 1 SEM-PLS analysis established that patient factors, family factors, family support, and health service quality collectively explain 86.7% of self-regulation variance and 80.7% of quality-of-life variance in a sample of 155 Indonesian T2DM patients. A novel sequential mediation pathway was empirically confirmed patient factors shape illness representations, which generate emotional responses, which in turn determine self-regulation behavior, which ultimately drives quality of life providing theoretically rich insights into the mechanisms through which individual cognitions and emotions translate into behavioral and clinical outcomes. Family support was identified as the strongest direct predictor of quality of life and the second strongest predictor of self-regulation, providing compelling empirical evidence for the strategic centrality of family engagement in T2DM management.
The resulting FCN-EL intervention module, structured across four Kolb experiential learning stages delivered over 12 weeks with active family co-participation, achieved perfect content validity (CVI = 1.00) and was judged by expert reviewers as clinically accurate, pedagogically sound, linguistically accessible, and practically implementable within the Indonesian primary healthcare system. These findings collectively provide a robust theoretical, empirical, and practical foundation for implementing family-engaged, experientially structured self-regulation programs in community health settings, with strong potential to significantly improve both the clinical and psychosocial outcomes of patients living with type 2 diabetes mellitus.

Author Contributions

L.M.: Conceptualization, data collection, formal analysis, writing original draft, project administration. T.S.: Supervision, methodology, writing review & editing. S.: Supervision, validation, writing review & editing. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest.

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