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The effectiveness of Schema therapy on Alexithymia, Cognitive flexibility, Body image, and Food craving in individuals with type 2 diabetes: A randomized controlled trial

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Abstract

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder accompanied by alexithymia, cognitive inflexibility, body image disturbances, and food craving. Schema therapy targets maladaptive cognitive-emotional schemas and may improve these psychosocial factors. We assessed group schema therapy for alexithymia, cognitive flexibility, body image, and food craving in adults with T2DM. Fifty adults were randomized to eight weekly 90-minute sessions of schema therapy or diabetes self-management education (DSMES), matched for therapist contact and format. Self-report measures (TAS-20, CFI, BICI, FCQ-T) were administered pre- and post-intervention. Data were analyzed using intention-to-treat with multiple imputation. ANCOVA adjusted for baseline scores. Schema therapy produced significant improvements over DSMES in alexithymia (adjusted means 49.31 vs 60.09; $p < 0.001$; $\eta^2p = 0.352$), body image (32.92 vs 39.21; $p < 0.001$; $\eta^2p = 0.258$), and food craving (92.30 vs 106.85; $p < 0.001$; $\eta^2p = 0.340$). Cognitive flexibility total improved (100.81vs 94.47; $p < 0.001$; $\eta^2p = 0.085$), but the Control subscale did not ($p = 0.128$). All subscales of alexithymia, body image, and food craving improved. Group schema therapy may be a useful adjunct for selected psychosocial barriers in T2DM, but sample size, no follow-up, and self-report measures limit conclusions.

Trial registration: IRCT20251201068177N1 (registered 31 December 2025).

Introduction

Type 2 diabetes mellitus (T2DM) is a progressive metabolic disorder characterized by chronic hyperglycemia and substantial long-term morbidity [1–4]. Effective management requires sustained adherence to medication, dietary recommendations, physical activity, and glucose monitoring [5]. These demands can contribute to psychological distress, while depression and diabetes distress are associated with difficulties in diabetes self-management and, in some studies, poorer glycemic outcomes [6,7]. Diabetes distress is also recognized as a distinct and clinically relevant construct in diabetes care [8]. Accordingly, identifying modifiable psychological processes relevant to self-regulation is clinically important.

Among these processes, alexithymia, cognitive flexibility, body-image concerns, and food craving represent distinct but potentially related domains. Alexithymia involves difficulties identifying and describing emotions and has been associated with poorer perceived social support and glycemic control in people with diabetes; however, the available evidence is predominantly cross-sectional [9]. Cognitive flexibility refers to the capacity to generate alternative responses and perceive situations as controllable [10]. and has been examined in T2DM in relation to mindfulness and emotion-regulation processes [11]. Body-image concerns may also be clinically relevant, although evidence specific to adults with T2DM remains limited; intervention research in non-diabetic populations nevertheless indicates that body-image disturbance can be modified psychologically [12]. Food craving is directly relevant to dietary self-regulation and has been associated with poor glycemic control in T2DM [13]. These outcomes were

therefore selected a priori to capture complementary domains of emotional processing, cognitive adaptation, self-evaluation, and eating-related self-regulation rather than a single nonspecific index of psychological distress.

Schema therapy (ST) provides a theoretically coherent framework for integrating these domains. Young's model conceptualizes early maladaptive schemas (EMSs) as enduring patterns of cognition, emotion, bodily experience, and behavior that arise when core emotional needs are insufficiently met and can shape maladaptive coping responses [14]. In T2DM, specific EMSs have been associated with blood-glucose-related outcomes and with differences between individuals with and without diabetes [15,16]. Importantly, a systematic review and meta-analysis found associations between EMSs, difficulties in emotion regulation, and alexithymia, supporting a link between schema-level processes and impaired emotional processing [17]. Research in eating-disorder populations has additionally identified associations among schema-related constructs, emotional regulation, and cognitive flexibility, although these findings are observational, concern early adaptive schemas, and cannot be directly generalized to T2DM [18]. Taken together, these findings provide a plausible theoretical pathway whereby rigid schema-based appraisals and coping responses may influence emotional awareness, cognitive flexibility, self-evaluation, and eating-related self-regulation.

ST directly targets EMSs through cognitive, experiential, behavioral, and interpersonal techniques, including cognitive restructuring, imagery, and behavioral pattern breaking [14,19]. This transdiagnostic focus is relevant because the selected outcomes may reflect different downstream manifestations of persistent maladaptive patterns: difficulties recognizing or expressing emotions may be linked to schema-related emotional inhibition [20]; rigid or threat-focused appraisals may constrain flexible responding [10,14]; negative self-evaluative patterns may contribute to body-image concerns; and schema-linked coping and emotion-regulation difficulties may affect eating-related behavior [17,18].

Evidence for psychological interventions in T2DM is encouraging but heterogeneous. Mindfulness-based interventions and acceptance and commitment therapy have shown beneficial effects on selected psychological outcomes, with variable effects on glycated hemoglobin (HbA1c) and substantial methodological heterogeneity[20,21]. The value of psychological interventions is supported by evidence from other chronic conditions; for example, group cognitive behavioral therapy (CBT) improved quality of life, depression, and well-being in Parkinson's disease [22,23]. Group-based diabetes self-management education and support (DSMES) improves self-management and self-efficacy, although effects on quality of life are less consistent [24]. In contrast, evidence for ST in T2DM remains limited. One earlier controlled study reported reduced food craving following ST in obese women with T2DM, but examined a different outcome set and a specific obese female sample [25]. Modified protocols (mindfulness-based, mode-based) have been examined only in small quasi-experimental studies. Moreover, mindfulness and acceptance-based interventions, though beneficial, do not directly target schema-driven emotional, self-evaluative, and eating-related processes [20,21]. Thus, no study has simultaneously examined whether group schema therapy improves alexithymia, cognitive flexibility, body image, and food craving in T2DM.

This trial addresses that gap. DSMES was chosen as the control to match therapist contact, group format, and duration, isolating schema-specific effects. We hypothesised that group schema therapy would lead to greater improvements than DSMES in alexithymia, cognitive flexibility, body image, and food craving, after adjusting for baseline scores. Subscale consistency was explored without testing mediators.

Results

Participant Flow and Baseline Characteristics

Of the 50 randomized participants, 45 completed the post-test assessment (Schema Therapy group, n = 22; Control group, n = 23). The remaining five participants had missing post-test outcome data and were retained in the intention-to-treat analysis through multiple imputation. The participant flow is presented in Fig. 1.

All 50 randomized participants were included in the intention-to-treat (ITT) analysis. Missing post-test outcome data were handled using multiple imputation, with five imputed datasets generated using fully conditional specification. The imputed datasets were analyzed using the prespecified ANCOVA models, and pooled estimates were used for inference. Baseline demographic and clinical characteristics were generally comparable between the treatment groups. A statistically significant difference was observed in age, with participants in the Schema Therapy group being older than those in the control group (53.14 ± 7.70 vs. 48.80 ± 6.45 years, $p = .037$; Glass's $\Delta = 0.672$). No statistically significant between-group differences were observed in sex, marital status, diabetes duration, education, or insulin use (Table 1).

Table 1
Demographic characteristics of participants by group (ITT population, N = 50)

Variable	Category	Schema Therapy	Control	P	Effect size
Age (year)	-	53.14 ± 7.7	48.80 ± 6.45	0.037	0.672†
Gender	Female	20 (80.0%)	19 (76.0%)	0.733	0.048#
	Male	5 (20.0%)	6 (24.0%)		
Marital Status	Married	23 (92.0%)	23 (92.0%)	1.000	0.000#
	Single	2 (8.0%)	2 (8.0%)		
Duration of diabetes (year)	-	10.18 ± 4.49	8.96 ± 2.92	0.261	0.417†
Education	Diploma	14 (56.0%)	10 (40.0%)	0.316	0.266#
	MA	3 (12.0%)	8 (32.0%)		
	BC	6 (24.0%)	4 (16.0%)		
	MC	2 (8.0%)	3 (12.0%)		
Insulin use		2 (8.0%)	1 (4.0%)	0.552	0.084#

• †Glass's delta (using control group standard deviation)

• #Cramer's V

• Data are presented as Mean ± SD or N (%). All analyses are based on the Intention-to-Treat (ITT) population after imputation of missing baseline demographic data (age, diabetes duration, education, and insulin). P-values are derived from independent-samples t-tests for continuous variables and Chi-square tests for categorical variables (Fisher's exact test reported when expected cell count < 5)

Intervention Effects on Components

To account for baseline imbalances, all primary and secondary outcome analyses were conducted using ANCOVA. In these models, the corresponding baseline (pre-test) scores were entered as covariates. The adjusted effects of the intervention on psychological characteristics, including alexithymia, cognitive flexibility, body image, and food craving, are presented in Tables 2 and 3.

Table 2
Exploratory effects of intervention on Alexithymia, cognitive flexibility, and body image and their components: ITT analysis with multiple imputation (N = 50)

Characteristics	Group	Adjusted Mean	SE	p (Group)	η²p (95% CI)	F
Alexithymia	INT	49.31	0.630	< 0.001	0.352 (0.259–0.442)	144.780
	CTRL	60.09	0.620			
• DIF	INT	18.09	0.283	< 0.001	0.183 (0.105–0.270)	59.925
	CTRL	21.18	0.277			
• DDF	INT	12.87	0.272	< 0.001	0.139 (0.070–0.222)	43.277
	CTRL	15.39	0.266			
• EOT	INT	19.51	0.414	< 0.001	0.075 (0.025–0.145)	21.792
	CTRL	22.21	0.404			
Cognitive Flexibility	INT	100.81	0.911	< 0.001	0.085 (0.031–0.157)	24.843
	CTRL	94.47	0.891			
• ALT	INT	72.67	0.788	< 0.001	0.071 (0.022–0.139)	20.313
	CTRL	67.70	0.773			
• CON	INT	26.85	0.487	0.128	0.009 (0.000-0.044)	2.335
	CTRL	27.93	0.476			
Body Image	INT	32.92	0.463	< 0.001	0.258 (0.170–0.349)	92.961
	CTRL	39.21	0.453			
• DAC	INT	18.23	0.299	< 0.001	0.197 (0.116–0.285)	65.391

Characteristics	Group	Adjusted Mean	SE	p (Group)	η²p (95% CI)	F
	CTRL	21.65	0.292			
• SI	INT	14.60	0.246	< 0.001	0.226 (0.141–0.315)	77.828
	CTRL	17.64	0.241			

• Note: Values are adjusted means (estimated marginal means) derived from ANCOVA with baseline (pre-test) scores as a covariate, using the Intention-to-Treat (ITT) population (N = 50) after Multiple Imputation (MI) for missing outcome data.

• Abbreviations: INT= Schema therapy group; CTRL = Control group; SE = Standard Error; η²p= Partial Eta Squared; F = F-statistic; p (group) = p-value for between-group comparison (Group effect); DIF = Difficulty Identifying Feelings; DDF = Difficulty Describing Feelings; EOT = Externally Oriented Thinking; ALT = Alternatives; CON = Control; DAC = Dysmorphic Appearance Concern; SI =Symptom Interference

• Covariates: For each outcome, the corresponding pre-test score was entered as a covariate in the ANCOVA model to adjust for baseline imbalances.

• Effect size: Partial Eta Squared (η²p) is reported as a measure of effect size.

• Missing data: Handled using Multiple Imputation (MI) with 5 imputed datasets under the Fully Conditional Specification (MCMC) method.

• Significance: All p-values are two-tailed, and values less than 0.05 were considered statistically significant.

• Alexithymia total is the primary outcome. All other outcomes in this table are exploratory secondary or subscale outcomes. No adjustment for multiple comparisons was applied in the primary analysis. A Benjamin–Hochberg FDR sensitivity analysis (q < 0.10) is provided in Supplementary Table S1

Table 3
Exploratory effects of intervention on food craving and components: ITT analysis with multiple imputation (N = 50)

Characteristics	Group	Adjusted Mean	SE	p (Group)	η²p (95% CI)	F
Food Craving	INT	92.30	0.876	< 0.001	0.340 (0.247–0.430)	137.749
	CTRL	106.85	0.856			
• LOC	INT	25.88	0.433	< 0.001	0.271 (0.182–0.362)	99.208
	CTRL	31.98	0.423			
• PRE	INT	17.12	0.262	< 0.001	0.083 (0.030–0.155)	24.213
	CTRL	18.93	0.256			
• PHY	INT	26.12	0.599	< 0.001	0.102 (0.042–0.177)	30.229
	CTRL	30.75	0.586			
• EMO	INT	9.04	0.256	< 0.001	0.123 (0.057–0.202)	37.317
	CTRL	11.23	0.250			
• GUILT	INT	13.25	0.232	< 0.001	0.091 (0.035–0.165)	26.835
	CTRL	14.93	0.227			

• Note: Values are adjusted means (estimated marginal means) derived from ANCOVA with baseline (pre-test) scores as a covariate, using the Intention-to-Treat (ITT) population (N = 50) after Multiple Imputation (MI) for missing outcome data.

• Abbreviations: INT = Schema Therapy group; CTRL = Control group; SE = Standard Error; η²p = Partial Eta Squared; F = F-statistic; p (group) = p-value for between-group comparison; LOC = Lack of Control over eating; PRE = Preoccupation with food; PHY =Craving as a physiological state; EMO = Emotions before or during food craving; GUILT = Guilt from cravings and for giving in to them.

• Covariates: For each outcome, the corresponding pre-test score was entered as a covariate in the ANCOVA model to adjust for baseline imbalances.

• Effect size: Partial Eta Squared (η²p) is reported as a measure of effect size.

• Missing data: Handled using Multiple Imputation (MI) with 5 imputed datasets under the Fully Conditional Specification (MCMC) method.

Characteristics	Group	Adjusted Mean	SE	p (Group)	η²p (95% CI)	F
• Significance: All p-values are two-tailed, and values less than 0.05 were considered statistically significant.						
• Alexithymia total is the primary outcome. All other outcomes in this table are exploratory secondary or subscale outcomes. No adjustment for multiple comparisons was applied in the primary analysis. A Benjamin–Hochberg FDR sensitivity analysis (q < 0.10) is provided in Supplementary Table S1						

Effect sizes were interpreted using Cohen's benchmarks for partial eta-squared (small ≈ 0.01, medium ≈ 0.06, large ≈ 0.14). The between-group effect was large for alexithymia (η^2p = 0.352, 95% CI 0.259–0.442), body image (η^2p = 0.258, 95% CI 0.170–0.349), and food craving (η^2p = 0.340, 95% CI 0.247–0.430). For cognitive flexibility, the total effect was medium (η^2p = 0.085, 95% CI 0.031–0.157), while the 'Alternatives' subscale showed a medium effect (η^2p = 0.071, 95% CI 0.022–0.139) and the 'Control' subscale showed a small effect (η^2p = 0.009, 95% CI 0.000-0.044). All subscale effects for alexithymia, body image, and food craving ranged from small to large, with the majority in the medium-to-large range.

A complete-case sensitivity analysis (CCA) restricted to the 45 participants who completed the post-intervention assessment produced results consistent with the primary ITT analysis for alexithymia, body image, and food craving. For cognitive flexibility and some secondary subscales (EOT, CF total, ALT, PRE), the CCA estimates were borderline non-significant (p = 0.055–0.083), while the direction of effects remained unchanged. Full ITT and CCA estimates for all outcomes are presented in (Supplementary Table S). Exploratory secondary and subscale outcomes were also examined using a Benjamin–Hochberg false discovery rate sensitivity analysis (q < 0.10; 15 comparisons; (Supplementary Table S1). All secondary and subscale outcomes except the Cognitive Flexibility Inventory 'Control' subscale survived FDR correction. Specifically, all TAS-20 subscales (DIF, DDF, EOT), body image total and subscales (DAC, SI), food craving total and subscales (LOC, PRE, PHY, EMO, GUILT), cognitive flexibility total, and the 'Alternatives' subscale remained statistically significant after correction, as detailed in Supplementary Table S1. The 'Control' subscale did not survive correction (unadjusted p = 0.128; BH-adjusted p = 0.128). These findings should still be interpreted as exploratory and hypothesis-generating.

Discussion

The present randomized controlled trial found that an eight-session group schema therapy intervention improved several psychological outcomes among adults with type 2 diabetes mellitus (T2DM). Significant between-group improvements were observed in alexithymia, body image concerns, and food craving. Cognitive flexibility also improved significantly at the total-score level, although this effect was driven entirely by the 'Alternatives' subscale, whereas the 'Control' subscale did not reach statistical significance. Importantly, the control condition consisted of structured diabetes self-management education and support (DSMES) rather than a no-treatment or waitlist condition. This active control design strengthens the validity of the observed intervention effects, as improvements in the schema therapy group occurred over and above the benefits of structured diabetes education. These findings are

consistent with the broader schema therapy literature, although that literature remains heterogeneous in terms of clinical populations, intervention formats, treatment intensity, and outcome measures [26].

The most consistent finding concerned alexithymia. This is of particular interest because alexithymia is relatively common in T2DM, with a pooled prevalence of 43.0% (95% CI 35.0–51.0%) and a pooled mean TAS-20 score of 57.70 (95% CI 55.25–60.15) [27], addressing a psychological characteristic relevant to a substantial proportion of this population. The observed reduction is theoretically compatible with evidence linking alexithymia to early maladaptive schemas: a meta-analysis of 19 studies (n = 5,957) found alexithymia positively associated with 16 of 18 schemas, particularly those related to unmet attachment and autonomy needs [17]. This evidence provides a plausible conceptual rationale for a schema-focused intervention targeting persistent cognitive-emotional patterns.

The differential pattern across TAS-20 dimensions is also noteworthy. Difficulties identifying and describing feelings improved significantly, along with externally oriented thinking (all $p < 0.001$). This indicates that improvements were observed across all three dimensions of the TAS-20. The effect sizes for these subscales ranged from small to moderate (partial $\eta^2p = 0.075$ to 0.183), suggesting that the intervention had a broad rather than isolated effect on different facets of alexithymia. The improvement in the total cognitive flexibility score was statistically significant ($p < 0.001$). However, this overall effect was driven entirely by the 'Alternatives' subscale ($p < 0.001$), whereas the 'Control' subscale did not reach statistical significance ($p = 0.128$). Given the modest sample size, no conclusion can be drawn regarding the effect of schema therapy on perceived control, and the null result should not be interpreted as evidence of no effect. The study may have been underpowered to detect small effects on this subscale. The present findings suggest that schema therapy may enhance the ability to generate alternative cognitive perspectives, but the effect on perceived control remains undetermined and requires confirmation in an adequately powered trial. A meta-analysis of cognitive performance in people with T2DM reported poorer performance in several executive domains, including cognitive flexibility, compared with individuals without diabetes [28]. The present finding that the 'Alternatives' component improved while the 'Control' component did not may be consistent with an effect on cognitive avoidance or rigidity in generating options, rather than general executive control functions; however, this interpretation requires direct testing.

However, these interpretations are post-hoc and should be examined in future studies specifically designed to test cognitive mediators. These findings are broadly consistent with a previous randomized controlled trial among 32 adults with obesity reporting significant improvements in body image following schema therapy [29], although the population and clinical context differed substantially. The convergence in the direction of findings supports further investigation of schema therapy for body-related psychological difficulties. The results may be understood within the schema framework, in which persistent maladaptive self-evaluative patterns influence how individuals interpret themselves and their experiences. The distinction between statistical and clinical significance is important. Published reference values for the BICI include a cut-off of 55 derived from a routine mental-health population, but

this value is a reference threshold rather than a minimal clinically important difference (MCID) [30]. Because a validated MCID for the BICI specifically in adults with T2DM was not established in the present study, the magnitude of the statistically significant change cannot be directly translated into a patient-important clinical benefit [31]. The present findings therefore support statistical improvement while leaving the clinical importance of that improvement to be established in future research.

Food craving is a multi-determined construct influenced by emotional states, learned responses, cognitive processes, and physiological conditions [32]. In diabetes, physiological factors may also contribute; for example, an experimental study in adults with type 1 diabetes found that acute hypoglycemia increased the prevalence and intensity of food cravings, particularly for carbohydrate-rich foods [33]. Because the present study did not assess hypoglycemia episodes or glycemic fluctuations, these physiological mechanisms cannot be evaluated here. The present findings are relevant to the schema therapy model. Previous systematic evidence has linked early maladaptive schemas with eating-related psychopathology, and schema therapy has been proposed as a potentially useful approach for addressing persistent emotional and behavioral patterns associated with disordered eating [34,35]. However, the study measured craving rather than eating behavior, dietary adherence, caloric intake, or glycemic outcomes; therefore, the observed reduction should not be interpreted as evidence of improved dietary adherence or glycemic control. The pattern of effects may indicate that the intervention was more pronounced for emotional, self-evaluative, and eating-related psychological processes than for cognitive flexibility. Because these outcomes represent distinct psychological constructs, this pattern should not be interpreted as evidence that schema therapy has a uniformly distributed effect across all domains. While the observed improvements in alexithymia, body image, and food craving are theoretically consistent with schema therapy's proposed mechanisms, the present trial did not directly measure early maladaptive schemas, emotional regulation, or other candidate mediators. Therefore, these findings cannot establish that schema modification mediated the observed changes. These mechanisms should be tested in future process-oriented trials with pre-specified mediation models.

These findings suggest that group schema therapy may be considered as an adjunct to standard diabetes self-management education for adults with T2DM who present with alexithymia, body image concerns, or food craving. In practice, diabetes clinics could screen for these psychosocial factors and offer a brief, structured eight-session group program alongside routine care. However, schema therapy should not replace DSMES. Future research should priorities larger, multicenter randomized controlled trials with longer follow-up (e.g., 6–12 months) to assess durability. Such trials should also include objective clinical outcomes (e.g., HbA1c) and test pre-specified mediating mechanisms, particularly changes in early maladaptive schemas and emotion regulation, to clarify how schema therapy produces its effects.

Several limitations should be considered. First, the small sample size limits statistical power to detect smaller effect sizes. The sample size calculation relied on an effect size estimate derived from a study in patients with chronic kidney disease [36], which may not accurately reflect the expected effect in T2DM.

We conservatively recruited 25 participants per group (N = 50), exceeding the calculated requirement of 14 per group, which partially mitigates this concern. The study was adequately powered for outcomes with large effect sizes, but power may have been insufficient for several secondary measures, particularly the 'Control' subscale of cognitive flexibility. Therefore, the non-significant findings in these domains should be interpreted with caution and require confirmation in future studies with larger samples.

Second, the external validity of the findings is limited by sample characteristics. Requiring a high school diploma excluded patients with lower health literacy, who face greater barriers to diabetes self-management. The predominantly female sample (78%), single-center recruitment, and convenience sampling further restrict generalizability to male patients, other settings, and more diverse populations. These limitations mean the observed benefits of schema therapy should be considered specific to this sample profile. Future trials should include lower-literacy patients, recruit more men, and use multicenter sampling. Third, all principal outcomes were assessed using self-report questionnaires, which may introduce reporting or social-desirability biases. Although the statistical consultant was blinded to treatment allocation, the interviewers who administered the questionnaires were not blinded, owing to practical constraints. However, because participants completed the questionnaires directly and were themselves unblinded to treatment condition, the additional risk of interviewer-induced bias is likely minimal. The use of validated instruments and blinded statistical analysis further mitigates this concern. Nonetheless, the absence of interviewer blinding should be acknowledged as a minor methodological limitation. Relatedly, independent fidelity assessment via recorded sessions was not feasible; however, fidelity was monitored independently by a Schema Therapy-trained supervisor not involved in intervention delivery, and manualized protocols were used. This provides reasonable assurance of treatment fidelity, although independent verification through session recordings remains a limitation. Fourth, five participants (10%) had missing post-intervention outcome data. Although multiple imputation was applied in the primary intention-to-treat analysis and complete-case sensitivity analyses yielded consistent results for the primary outcomes (Supplementary Table S2), the possibility of bias arising from non-random missingness cannot be definitively excluded. The missing-at-random assumption underlying multiple imputation is not empirically verifiable; consequently, the extent to which the findings are robust to alternative missing-data mechanisms remains uncertain.

Fifth, objective indicators of diabetes control, including HbA1c, fasting glucose, or continuous glucose monitoring, were not assessed. Consequently, the present study cannot determine whether psychological changes were accompanied by improved glycemic control or other metabolic benefits. Sixth, several potentially prognostic clinical variables, including subclinical depressive symptoms, full treatment regimen, and diabetes-related complications, were not comprehensively assessed. Although randomization reduces systematic baseline differences, residual confounding cannot be ruled out, and the observed effects should be interpreted with caution. Seventh, no post-intervention follow-up was conducted, preventing assessment of the durability of the observed effects. A follow-up period of at least 3 months would be necessary to evaluate whether the improvements persist over time. Future trials should incorporate longer-term follow-up assessments to establish the maintenance of treatment gains

and to inform clinical recommendations. Eighth, despite randomization, a statistically significant age difference was observed between the schema therapy and control groups. This difference may have influenced the observed outcomes, and the findings should therefore be interpreted with this limitation in mind.

Methods

The study protocol was approved by the Ethics Committee of Islamic Azad University, Najaf Abad Branch (IR.IAU.KHSH.REC.1404.095) on 15 July 2025. All procedures were performed in accordance with the Declaration of Helsinki and relevant national guidelines. Written informed consent was obtained from all participants prior to enrollment. The trial was registered with the Iranian Registry of Clinical Trials (IRCT; registration number: IRCT20251201068177N1) on 31 December 2025. Participant recruitment and the 8-week group intervention commenced in January 2026 at the Isfahan Endocrine and Metabolism Research Center (IEMRC), Iran.

This was a two-arm, parallel-group randomized controlled trial. The study adheres to the CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting randomized controlled trials (Supplementary Table S3). The trial protocol and statistical analysis plan are available from the corresponding author upon reasonable request. The study population comprised patients referred to the Isfahan Endocrine and Metabolism Research Center (IEMRC) in Isfahan, recruited via convenience sampling. Eligibility criteria required participants to be aged between 30 and 60 years, have a confirmed diagnosis of T2DM, and hold at least a high school diploma. This educational threshold ensured sufficient reading comprehension to complete the self-report questionnaires and understand the psychoeducational materials. Exclusion criteria were current psychiatric disorders or use of psychotropic medications, substance use disorders, and any medical condition that would preclude participation in group sessions. Psychiatric disorders were assessed via clinical interview and review of medical records. After obtaining written informed consent, 50 individuals were enrolled. The sample size was calculated based on the primary outcome, alexithymia, using data from a previous randomized controlled trial that evaluated the effect of schema therapy on alexithymia in patients with chronic kidney disease [36]. Based on the reported means and standard deviations in that study (57.33 ± 5.04 in the control group vs. 64.87 ± 5.51 in the intervention group), the effect size was calculated as Cohen's d = 1.43 using Stata software (version 17). With a two-tailed alpha of 0.05 and statistical power of 90%, the estimated required sample size was 11 participants per group. To account for an anticipated attrition rate of approximately 20%, the final target sample size was adjusted to 14 participants per group. We conservatively aimed to recruit 25 participants per group (total N = 50) to ensure adequate power even with higher-than-expected dropout.

Following recruitment, participants were randomly assigned to either the intervention or control group using a simple randomization sequence generated by the Random Allocation Software[37]. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes prepared by an independent statistical adviser not involved in the study. Participants and therapists were not blinded to

group allocation due to the nature of the interventions. The statistical consultant was blinded to treatment allocation throughout the analysis phase. The intervention was delivered over a period of eight weeks and was based on Young's Schema Therapy model[38]It incorporated cognitive, experiential, and behavioral techniques, including schema identification and validation, developmental formulation, schema-mode awareness, modification of maladaptive coping responses, strengthening of the Healthy Adult mode, self-compassion, and consolidation of adaptive responses. Schema Therapy-specific relational strategies, including empathic confrontation and limited reparenting, were used throughout the intervention as clinically appropriate. A detailed session-by-session description is provided in Supplementary Table S4. The Schema Therapy sessions were delivered by a clinical psychologist with two years of experience in Emotion-Focused Therapy and schema-focused therapies, who had completed 60 hours of specialized training in Young's Schema Therapy protocol. The therapist received weekly supervision from a Schema Therapy-trained supervisor not involved in direct intervention delivery.

Participants allocated to the control group received group-based diabetes self-management education (DSMES) sessions, each lasting 90 minutes, delivered over a period of eight weeks (eight weekly sessions). The educational program was structured in accordance with the 2022 National Standards for Diabetes Self-Management Education and Support [5] and was designed to provide standardized education regarding diabetes management and lifestyle-related self-care. The curriculum addressed diabetes and its treatment, healthy eating and meal planning, physical activity, medication and insulin use, blood glucose monitoring, prevention of acute and chronic diabetes-related complications, and practical diabetes self-management in daily life. The content of the eight sessions is detailed in (Supplementary Table S5) The DSMES sessions were delivered by a clinical psychologist with a Master's degree in Clinical Psychology who had received training in diabetes self-management education, with clinical oversight provided by an endocrinologist. Treatment fidelity and adherence were monitored prospectively in both study arms using prespecified, session-specific checklists. For the Schema Therapy intervention, adherence to core protocol components was documented using a structured checklist and reviewed during weekly supervision by the Schema Therapy-trained supervisor (Supplementary Table S6). For the DSMES control condition, sessions followed a predefined educational manual, and delivery of core educational content was documented using session-specific checklists (Supplementary Table S7). Attendance was recorded for all participants in both groups. Independent fidelity assessment via recorded sessions was not feasible due to practical constraints. However, adherence was monitored independently by a Schema Therapy-trained supervisor who was not involved in intervention delivery, using structured checklists and weekly supervision.

To assess the primary and secondary outcomes, data were collected at baseline and immediately post-intervention using four validated self-report instruments: the Toronto Alexithymia Scale (TAS-20) [39], the Cognitive Flexibility Inventory (CFI) [10], the Body Image Concern Inventory (BICI) [40], and the Food Craving Questionnaire—Trait version (FCQ-T) [41]. All primary and secondary outcomes were assessed using validated self-report questionnaires completed directly by the participants. Therefore, no independent assessor-rated outcome measures were used. Because the two interventions differed in content,

participants could not be blinded to treatment allocation. To reduce potential analytic bias, the statistical consultant was blinded to treatment allocation during the statistical analysis, with treatment groups coded as A and B until completion of the analyses. Given the extensive psychometric detail required for each measure, comprehensive information regarding their developers, item numbers, factorial structures, scoring algorithms, interpretive frameworks, and psychometric properties (including reliability and validity indices) is presented in (Supplementary Table S8) to ensure complete transparency while preserving the readability of the main manuscript.

Missing baseline data were minimal, affecting only two participants (both in the intervention group) for age, education, diabetes duration, and insulin; no baseline missing data were observed in the control group. For continuous variables (age and diabetes duration), we used regression-based imputation with treatment group, gender, and the other continuous variable as predictors. For categorical variables (education and insulin), missing values were replaced with the mode within the intervention group. Regarding outcome data, 5 participants (3 in the Schema therapy group and 2 in the Control group) had missing post-test scores. The reasons for dropout are detailed in the trial profile (Fig. 1). Following the ITT principle, we performed our primary analysis on all 50 participants using Multiple Imputation (MI) with 5 imputed datasets. Regarding outcome data, 5 participants (3 in the Schema therapy group and 2 in the Control group) had missing post-test scores. The reasons for dropout are detailed in the trial profile (Fig. 1). Following the ITT principle, we performed our primary analysis on all 50 participants using Multiple Imputation (MI) with 5 imputed datasets. To assess the robustness of our findings, we also conducted a complete-case analysis (CCA) as a sensitivity analysis, including only the 45 participants who completed the trial. The CCA results were consistent with the primary ITT analysis across all outcomes, confirming that our findings were not substantially influenced by the handling of missing data (Supplementary Table S2).

All data were analyzed using SPSS version 27 (IBM Corp., Armonk, NY, USA). To minimize detection bias, the statistical consultant was blinded to treatment allocation throughout the analysis phase. The two groups were coded as 'A' and 'B', and the correspondence between these codes and the actual treatment groups was concealed until all statistical analyses were completed. The normality of residuals for the dependent variables was assessed using the Shapiro–Wilk test, and homogeneity of variances was verified using Levene's test. To satisfy the homogeneity of regression slopes assumption underlying the ANCOVA, the group-by-covariate interaction term was tested for each outcome. Baseline differences between groups were examined using independent t-tests and χ^2 tests, while within-group changes were assessed with paired t-tests. The primary inferential analysis was an analysis of covariance (ANCOVA) to compare post-test scores between the groups while controlling for their respective pre-test values. For the primary and key secondary outcomes, 95% confidence intervals for partial eta-squared were calculated using the non-central F distribution method to provide a more comprehensive effect size estimation.

The primary outcome (alexithymia) was analyzed without adjustment for multiple comparisons, as it was the sole pre-specified confirmatory outcome. All secondary outcomes and subscale analyses were

exploratory and were not adjusted for multiple comparisons; these findings are labeled as exploratory throughout and should be interpreted as hypothesis-generating. Effect sizes were interpreted using conventional benchmarks for partial eta-squared (small ≈ 0.01, medium ≈ 0.06, large ≈ 0.14). To evaluate the robustness of exploratory findings, a sensitivity analysis using the Benjamini-Hochberg (BH) false discovery rate (FDR) correction ($q < 0.10$) was applied across all secondary and subscale outcomes [42]. Results are presented in Supplementary Table S1. All analyses were conducted on an intention-to-treat (ITT) basis, as detailed in the Missing data section.

In summary, this randomized controlled trial found that an eight-session group schema therapy intervention improved several self-reported psychological outcomes among adults with T2DM. Statistically significant between-group improvements were observed in alexithymia, body image, and food craving across all measured dimensions. Cognitive flexibility showed a significant improvement in the 'Alternatives' component, but not in the 'Control' component. These findings suggest that schema therapy may be a useful adjunctive intervention for selected psychosocial barriers in T2DM, particularly emotional, self-evaluative, and eating-related difficulties. However, definitive conclusions are precluded by the small sample size, single-center design, absence of long-term follow-up, and reliance on self-report measures. Future larger trials with longer follow-up and assessment of mediating mechanisms are needed to establish the clinical significance and durability of these effects.

Declarations

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

This study was performed in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Islamic Azad University, Najaf Abad Branch (IR.IAU.KHSH.REC.1404.095). Written informed consent was obtained from all individual participants included in the study.

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Author Contribution

Z.F. and H.N. conceptualized and designed the study. Z.F. was responsible for participant recruitment, data collection, and drafting the original manuscript. H.N. supervised the project, contributed to methodology and study design, and critically revised the manuscript. M.S. provided clinical supervision, contributed to resources, and reviewed and edited the manuscript. M.A. performed randomization, statistical analysis, and data interpretation, and reviewed and edited the manuscript. All authors contributed to the interpretation of data and critically revised the manuscript for important intellectual content. All authors read and approved the final manuscript. Z.F. and H.N. contributed equally as corresponding authors, with H.N. serving as the senior supervisor.

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Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary information files.

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Figures

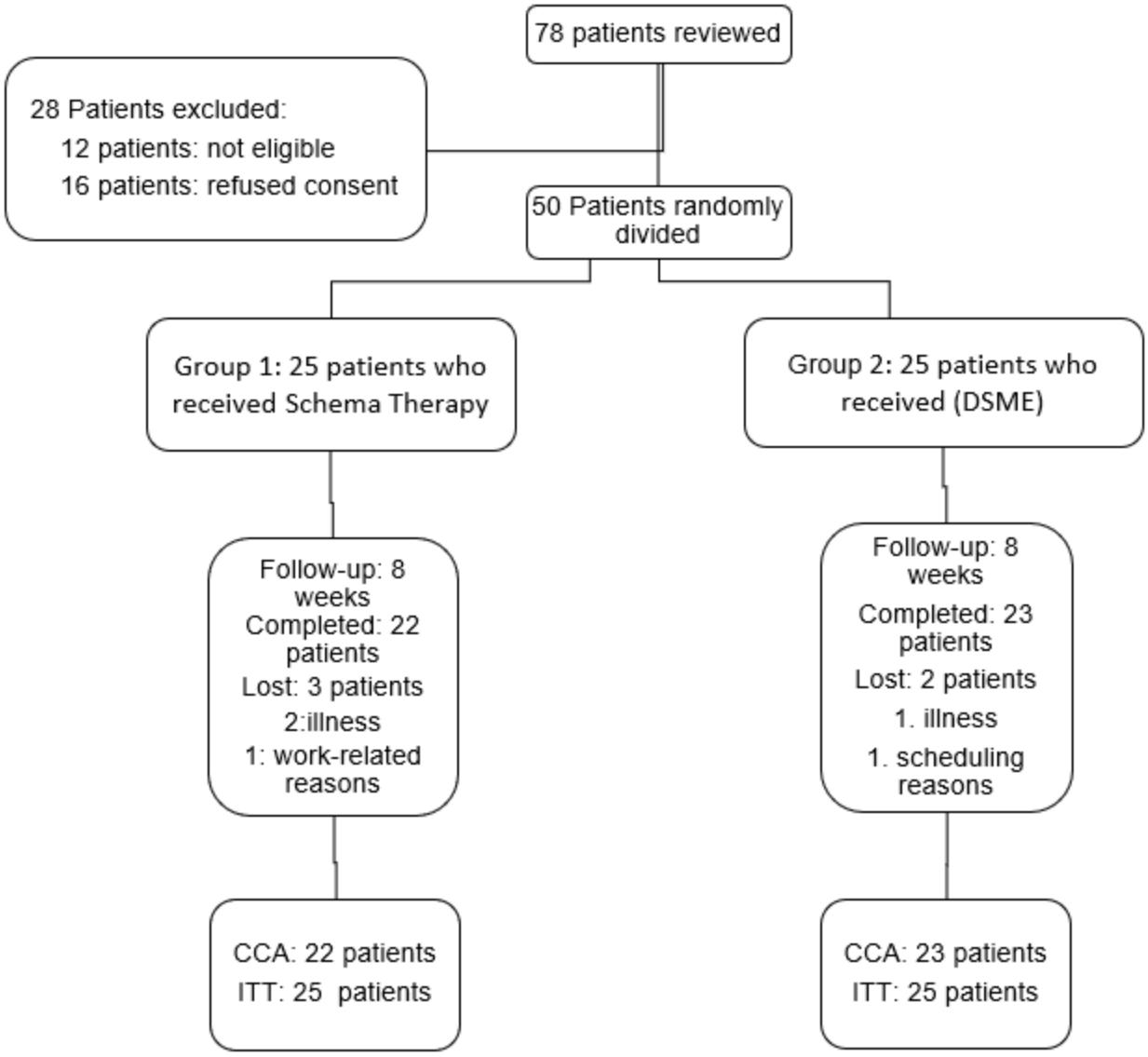


Figure 1

Trial profile

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