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**ADMINISTRATIVE INFORMATION**

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**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202570114

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2025 and was last updated on 28 July 2025.

**INTRODUCTION**

**Review question / Objective** To evaluate through meta-analysis the impact of nurse-led DSME on glycemic control, lipid profiles, and self-efficacy in adults with T2DM.

**Condition being studied** The global prevalence of type 2 diabetes mellitus (T2DM) continues to rise, with its complications posing significant threats to patient health and imposing substantial socioeconomic burdens. Diabetes Self-Management Education (DSME) is a cornerstone strategy for improving glycemic control, yet its clinical effectiveness is often limited by suboptimal adherence. Nurse-led DSME has garnered increasing attention due to its advantages in continuity of care and professional education, though its specific contributions remain debated.

**METHODS**

**Participant or population** Category Inclusion Criteria Exclusion Criteria  
Population (P) Adults (≥18 years) with type 2 diabetes mellitus (T2DM) and without severe complications (e.g., end-stage renal disease) Gestational diabetes, type 1 diabetes, pediatric or adolescent patients  
Intervention (I) Nurse-led DSME (defined as ≥50% of educational content delivered directly by registered nurses, with at least 3 structured sessions) Nurses only assisting in blood glucose monitoring or medication dispensing without leading educational content  
Comparator (C) Usual care, no intervention, or other non-nurse-led DSME (e.g., physician- or dietitian-led education) Control groups receiving other structured interventions (e.g., multidisciplinary team interventions)

**Outcomes (O)** Primary outcome: HbA1c; Secondary outcomes: Self-efficacy (DMSES score), emergency department visits, quality of life (DQOL score) Studies reporting only non-quantifiable outcomes (e.g., descriptive satisfaction data)

**Study Design (S)** Randomized controlled trials (RCTs) with full text available Non-randomized trials, observational studies, case reports, reviews.

**Intervention** Intervention (I) Nurse-led DSME (defined as  $\geq 50\%$  of educational content delivered directly by registered nurses, with at least 3 structured sessions) Nurses only assisting in blood glucose monitoring or medication dispensing without leading educational content.

**Comparator** Comparator (C) Usual care, no intervention, or other non-nurse-led DSME (e.g., physician- or dietitian-led education) Control groups receiving other structured interventions (e.g., multidisciplinary team interventions).

**Study designs to be included** Study Design (S) Randomized controlled trials (RCTs) with full text available Non-randomized trials, observational studies, case reports, reviews.

**Eligibility criteria** A dual-phase screening methodology was implemented to ensure rigorous study identification. In the primary phase, two investigators independently evaluated bibliographic records (titles and abstracts) against the eligibility framework, excluding manifestly ineligible publications. Subsequently, all potentially relevant articles underwent comprehensive full-text appraisal by both reviewers applying the predetermined selection criteria. Inter-reviewer discrepancies at either stage were systematically reconciled through iterative consensus-building, with unresolved cases adjudicated by an experienced third investigator to achieve final determination. The selection process was documented according to PRISMA guidelines. For included studies, we extracted key data including study characteristics, intervention details, and outcomes using a standardized form. Missing data were obtained by contacting corresponding authors or estimated using Cochrane-recommended methods when necessary, with all extractions performed in duplicate to ensure accuracy.

**Information sources** An exhaustive search strategy was implemented across three major biomedical databases (PubMed, EMBASE, Web of Science) encompassing all available literature through February 2025, without linguistic filters.

**Main outcome(s)** Eight RCTs (reporting HbA1c outcomes) were included. Meta-analysis demonstrated: (1) Glycemic control: Nurse-led DSME significantly reduced HbA1c at 4-6 months (MD=-0.92, 95%CI: -1.44 to -0.41) and  $>6$  months (MD=-0.54, 95%CI: -0.86 to -0.23) ( $p<0.05$ ), but not at 0-3 months (MD=-0.22, 95%CI: -1.15 to 0.51). Fasting blood glucose (FBG) showed significant improvement (MD=-0.20, 95%CI: -0.36 to -0.03). (2) Self-efficacy: The intervention group demonstrated significantly enhanced self-efficacy (SMD=1.48, 95%CI: 1.04-1.92). (3) Lipid profiles: High-density lipoprotein (HDL) increased significantly (MD=0.27, 95%CI: 0.14-0.41), while total cholesterol (TC), triglycerides (TG), and low-density lipoprotein (LDL) showed no significant changes. (4) Considerable heterogeneity was observed (HbA1c:  $I^2=87.8\%$ ; self-efficacy:  $I^2=84.5\%$ ). Meta-regression suggested borderline significant influence of follow-up duration on effect size ( $p=0.059$ ). No significant publication bias was detected (Egger's test  $p=0.116$ ).

**Quality assessment / Risk of bias analysis** To investigate potential moderators of the observed heterogeneity, we conducted weighted meta-regression analyses with restricted maximum likelihood estimation. This approach specifically evaluated temporal effects by modeling follow-up duration as a continuous predictor of treatment effect magnitude (expressed as mean difference in HbA1c reduction). The regression incorporated study-level covariates including intervention duration (weeks), number of educational sessions, and mean participant age to control for potential confounding factors. The meta-regression (mixed-effects model,  $k = 8$ ) revealed significant residual heterogeneity ( $I^2 = 84.11\%$ ), but follow-up duration was not a statistically significant predictor ( $p = 0.059$ ), suggesting it did not substantially influence the effect size.

**Strategy of data synthesis** All analyses were conducted using R with the meta package. Continuous outcomes like HbA1c were analyzed using mean differences with 95% CIs, while dichotomous outcomes used odds ratios. Heterogeneity was quantified with  $I^2$  statistics, with  $I^2 \leq 50\%$  indicating use of fixed-effects models and  $I^2 > 50\%$  warranting random-effects models. We investigated sources of significant heterogeneity through subgroup analyses when present. Publication bias was assessed through funnel plot symmetry and Egger's test, with  $p < 0.10$  considered suggestive of potential bias.

**Subgroup analysis** Eight randomized controlled trials comprising 1,654 participants contributed

HbA1c data, with two studies providing measurements at multiple time intervals. Considerable between-study heterogeneity was detected ( $I^2 = 87.8\%$ ), necessitating the application of a random-effects model for effect size estimation. To examine temporal patterns, we stratified the analysis by duration of follow-up: acute (0-3 months), intermediate (3-6 months), and extended (>6 months) periods.

Our stratified analysis revealed differential intervention effects across time horizons:

Acute phase (0-3 months): MD -0.22 (95% CI -1.15 to 0.51)

Intermediate phase (3-6 months): MD -0.92 (95% CI -1.44 to -0.41)

Extended phase (>6 months): MD -0.54 (95% CI -0.86 to -0.23)

These findings demonstrate statistically significant improvements in glycemic control favoring the intervention group during both intermediate and extended follow-up periods, while no significant between-group differences emerged during the initial three months post-intervention. The complete forest plot illustrating these effects appears in Figure 3.

We evaluated potential publication bias through both visual inspection of funnel plot symmetry and formal statistical testing using Egger's regression method ( $p=0.116$ ), with neither approach suggesting substantial bias in the reported HbA1c outcomes.

**Sensitivity analysis** Two studies reported FBG outcomes, with one study reporting two follow-up time points. No significant heterogeneity was detected, and the pooled effect size was MD = -0.20 (95% CI: -0.36, -0.03), indicating significantly lower FBG in the intervention group. The forest plot for FBG is presented in Figure 6. The funnel plot suggested potential small-study effects.

### 3.3.2 Lipid Profiles

Six studies reported TC, LDL, and HDL outcomes, while five studies reported TG outcomes. No significant heterogeneity was found, and fixed-effects models were applied. The pooled effect sizes were:

TC: 0.06 (95% CI: -0.08, 0.19)

TG: -0.01 (95% CI: -0.15, 0.13)

LDL: 0.10 (95% CI: -0.04, 0.23)

HDL: 0.27 (95% CI: 0.14, 0.41)

No significant differences were observed in TC, TG, or LDL between groups, but the intervention group had significantly higher HDL levels. The forest plot for lipid profiles is shown in Figure 8. Funnel plots indicated asymmetry, suggesting possible publication bias, but Egger's test was not performed due to the limited number of studies.

The funnel plots are presented in Figure 9. **3.3.3 Self-Efficacy**

Four studies reported self-efficacy outcomes, with significant heterogeneity ( $I^2 = 84.5\%$ ). A random-effects model yielded a pooled effect size of SMD = 1.48 (95% CI: 1.04, 1.92), indicating superior self-efficacy in the intervention group. The funnel plot suggested potential publication bias.

Meta-regression (mixed-effects model,  $k = 4$ ) showed significant residual heterogeneity ( $I^2 = 66.1\%$ ). Follow-up duration exhibited a marginally negative association with effect size ( $\beta = -0.244$ ,  $p = 0.059$ ), explaining 53.5% of heterogeneity.

**Country(ies) involved** China.

**Keywords** Type 2 diabetes mellitus; Diabetes self-management education; Nurse-led; Self-efficacy; Meta-analysis.

### Contributions of each author

Author 1 - Jiabao Sun.

Author 2 - Zhenwei Fan.

Author 3 - Mengyuan Kou.

Author 4 - Xuwei Wang.

Author 5 - Zhongmin Yue.

Author 6 - Min Zhang.