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## Glycaemic Index and Lifestyle-Based Management of Type 2 Diabetes in Adults: A Systematic Review and Meta-Analysis of Clinical Outcomes

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**ABSTRACT**

**Background:** Type 2 diabetes mellitus (T2DM) remains a significant global health challenge, disproportionately affecting individuals in low-income settings. Dietary interventions play a critical role in its management, with glycaemic index (GI) emerging as a key factor influencing glycaemic control.

**Objective:** This systematic review evaluates the effectiveness of low glycaemic index (LGI) diets compared to high glycaemic index (HGI) diets in managing T2DM among adults.

**Methods:** A comprehensive search was conducted across Cochrane Library, EMBASE, PubMed, and CINAHL databases for randomised controlled trials (RCTs) published between January 2004 and September 2016. No language restrictions were applied. Data extraction followed PRISMA guidelines, and analysis was performed using Review Manager 5.3. Risk of bias and study quality were assessed across all included trials.

**Results:** Six RCTs involving 604 adults met the inclusion criteria. Meta-analysis revealed that LGI diets led to a modest but statistically significant reduction in glycated haemoglobin (HbA1c) compared to HGI diets (mean difference: -0.11%; 95% CI: -0.22 to -0.01;  $p = 0.04$ ), based on a fixed-effect model.

**Conclusion:** Incorporating LGI dietary strategies into the nutritional management of adults with T2DM yields a small yet clinically meaningful improvement in glycaemic control. These findings support the integration of GI-based dietary planning into broader diabetes care frameworks.

**Keywords:** *Type 2 Diabetes Mellitus, Glycaemic Index, Glycaemic Control, HbA1c, Dietary Interventions, Systematic Review, Adult Diabetes Management*

**INTRODUCTION**

Diabetes mellitus has emerged as one of the most pressing global health challenges of the 21st century. Its burden has escalated dramatically over recent decades, fuelled by a complex interplay of demographic and lifestyle factors—including population growth, aging, urbanisation, declining physical activity, and rising obesity rates (Xie et al., 2022; Phelps et al., 2024). Type 2 diabetes mellitus (T2DM), the most prevalent form of the disease, is particularly concerning due to its insidious onset and strong association with modifiable risk factors. Individuals with a genetic predisposition who are exposed to high-risk environments—characterised by poor diet, sedentary behaviour, and metabolic dysfunction—are especially vulnerable (Ling, Bacos & Rönn, 2022).

Key contributors to the development of T2DM include abdominal obesity, low levels of high-density lipoprotein (HDL), physical inactivity, and conditions such as polycystic ovary syndrome (Blair, 2016). These risk factors are increasingly common in both high-income and low- and middle-income countries (LMICs), where rapid economic

and epidemiological transitions have intensified exposure. Between 1990 and 2019, the global incidence of diabetes rose by 13.4%, and the number of affected adults has tripled since 2000—reaching 537 million in 2021, with projections indicating continued growth (Ong et al., 2023; WHO, 2024). Alarming, approximately 95% of these cases are attributed to T2DM (Herman & Zimmet, 2012; Liu et al., 2022; He et al., 2024).

Beyond its clinical implications, diabetes imposes a substantial economic burden. Global treatment costs are estimated to range from \$673 billion to \$1.2 trillion annually, with per-patient expenditures varying widely—from as little as USD\$87 to nearly \$9,600—depending on access to medications, healthcare infrastructure, and the prevalence of complications (da Rocha Fernandes et al., 2016; Butt et al., 2024). These figures underscore the urgent need for cost-effective, scalable interventions that can be tailored to diverse populations.

Among the various strategies for managing T2DM—including pharmacological treatments, lifestyle modifications, and digital self-management tools—dietary

interventions have gained particular attention. In recent years, low glycaemic index (GI) diets have emerged as a promising approach for improving glycaemic control and reducing the risk of diabetes-related complications (Kaur et al., 2022; Sabarathinam, 2023). Unlike high-GI foods, which cause rapid spikes in blood glucose, low-GI foods are digested and absorbed more slowly, resulting in more stable postprandial glucose levels.

Type 2 diabetes, while common, is also largely preventable and manageable. It typically manifests in individuals over the age of 42 (Goyal et al., 2023), though it can develop at any stage of life. Many people live with the condition undiagnosed, unaware of its long-term consequences—including cardiovascular disease, neuropathy, and renal impairment (Evans et al., 2021). At its core, T2DM involves impaired glucose metabolism due to insufficient insulin production or insulin resistance (Becker & Goldfine, 2015), making dietary regulation a cornerstone of effective management.

This systematic review investigates the comparative efficacy of low versus high GI diets in reducing blood glucose levels among adults diagnosed with T2DM. It aims to establish the strength of evidence supporting low-GI dietary interventions as a means of improving glycaemic control. To achieve this, the review identifies and synthesises relevant studies, evaluates the impact of GI-

based dietary patterns on blood glucose regulation, and assesses the effectiveness of low-GI diets in clinical practice. It also explores the potential risks associated with high-GI diets and conducts a comparative analysis of outcomes across selected trials. The underlying hypothesis posits that low-GI diets contribute to significant and measurable improvements in glycaemic control when compared to high-GI dietary approaches.

## METHODS

### Review Question

The review focused on the following research question: What is the evidence for low glycaemic index diets as an intervention compared to high glycaemic index diets in lowering blood glucose levels in adults with type 2 diabetes mellitus?

### Eligibility Criteria

This systematic review was guided by the PICO framework—Population, Intervention, Comparator, and Outcome—which is widely used to structure clinical research questions and inform eligibility criteria (NIH, 2016). The framework provided a clear basis for selecting studies that addressed the effectiveness of dietary glycaemic index (GI) interventions in managing type 2 diabetes mellitus (T2DM) among adults.

**Table 1: Applying PICO Framework to Study Selection**

|              |   |
|--------------|---|
| Population   | Adults diagnosed with T2DM, irrespective of gender, ethnicity, or geographic location. Studies were eligible if participants were aged 18 years or older and had a confirmed diagnosis of type 2 diabetes.  |
| Intervention | Low glycaemic index diets, defined as dietary patterns predominantly composed of foods with a GI value between 0 and 55. These diets aim to reduce postprandial glucose spikes and improve long-term glycaemic control.   |
| Comparator   | High glycaemic index diets, characterised by foods with a GI value of 70 or above. These diets are known to produce rapid increases in blood glucose levels and were used to assess relative efficacy.  |
| Outcome      | Measurable reduction in blood glucose levels, typically assessed through biomarkers such as glycated haemoglobin (HbA1c) or fasting plasma glucose.   |
| Setting      | Eligible studies were conducted in a variety of settings, including home-based, hospital, and community environments, reflecting the real-world applicability of dietary interventions.   |
| Study design | Only randomised controlled trials (RCTs) were included, as they represent the gold standard for evaluating intervention efficacy. This design ensured methodological rigour, provided the highest level of evidence for intervention efficacy, and minimised bias in assessing the impact of GI-based dietary strategies on glycaemic outcomes. |

### Selection Criteria for Studies

To ensure methodological rigour and relevance, studies included in this systematic review focused on human participants with a mean age greater than 40 years, reflecting the increased risk of developing type 2 diabetes mellitus (T2DM) in middle-aged and older adults (NHS, 2016).

Studies were included if they directly compared low glycaemic index (GI) diets—defined as diets composed of foods with GI values between 0 and 55—with high GI diets, typically comprising foods with GI values of 70 or above. The intervention had to be delivered in real-world settings, including home-based, hospital, or community environments, to ensure ecological validity. Furthermore, studies were required to report outcomes related to blood glucose levels, specifically over a follow-up period of at least eight weeks, allowing for sufficient time to observe meaningful changes in glycaemic control.

Only peer-reviewed publications dated between January 2004 and September 2016 were considered. This 12-year window was selected to capture a comprehensive body of literature during a period of growing interest in GI-based dietary interventions.

Studies were excluded if they were non-randomised, involved participants with gestational diabetes, type 1 diabetes, hypoglycaemia, or hyperglycaemia, or included individuals with other non-communicable diseases such as cancer or chronic respiratory conditions (cardiovascular diseases were not grounds for exclusion). Trials that used pharmacological treatments or insulin injections as comparators were also excluded to isolate the dietary effect.

### Evaluation of Outcome Measures

The primary outcome measure was glycated haemoglobin (HbA1c), a well-established biomarker for long-term glycaemic control. Both baseline HbA1c values and post-intervention changes were assessed, with results consistently reported in percentage units across studies.

### Data Extraction and Statistical Instruments

Continuous data were extracted from each included study to facilitate meta-analysis. Key statistical parameters included mean differences between intervention and control groups, standard deviations (SD), standard error of the mean (SEM), p-values, confidence intervals, and total sample sizes. In cases where SDs were not reported, they were calculated using the Review Manager (RevMan) calculator to ensure consistency and completeness of the dataset.

### Search Strategy

A comprehensive literature search was conducted to identify relevant studies examining the effects of low glycaemic index (GI) diets on blood glucose levels in adults with type 2 diabetes mellitus (T2DM). The search spanned multiple electronic databases, including the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medical Literature Analysis and Retrieval System Online (MEDLINE), Excerpta Medica Database (EMBASE), and the Cochrane Database of Systematic Reviews (CDSR). The search period covered publications from 30 January 2004 to 14 September 2016, with no language restrictions applied to maximise inclusivity and minimise selection bias.

Additional sources were explored to ensure comprehensive coverage. These included Google Scholar, JSTOR, ScienceDirect, Web of Science, the University of Chester library database, and relevant grey literature. Manual searches of printed journals and reference lists from existing literature reviews were also performed to identify studies not captured through electronic means and to reduce the risk of publication bias.

Initial search terms were derived from the health condition of interest, the dietary intervention, and the primary outcome. The core terms included “type 2 diabetes,” “glyc\* index diet,” and “blood glucose.” The wildcard asterisk (\*) was used to capture variations in spelling and word endings, such as “glycaemic” (UK spelling) and “glycemic” (US spelling), ensuring a broader and more inclusive search.

Boolean operators were employed to refine the search strategy: “AND” was used to combine key concepts, “OR” to include term variations, and “NOT” to exclude irrelevant records (Lee, Kin, Kim & Lee, 1993). The PICO framework guided the selection of search terms, with variations for the population including “adults,” “human,” “men,” and “women.” Intervention-related terms included “low glycaemic index diet,” “low carbohydrate diets,” and “high fibre diets.” Outcome-related terms encompassed “blood glucose level” and “glycaemic control,” while the study design was specified as “randomised controlled trials.”

The final search string used to retrieve eligible studies was: “type 2 diabetes” AND “low glyc\* index diet” AND “high glyc\* index diet” AND “blood glucose level” AND “adults” AND “randomised controlled trials” NOT “systematic review and meta-analysis.” Searches were conducted on 13 and 14 September 2016.

## Study Selection

The selection process for eligible studies followed a structured and rigorous approach. Titles and reference lists retrieved from the four primary electronic databases—CINAHL, MEDLINE, EMBASE, and CDSR—were initially screened against the predefined eligibility criteria. In cases where titles were ambiguous or unclear, abstracts were reviewed to determine relevance. Studies that failed to meet the inclusion criteria were excluded, while full-text articles deemed potentially relevant were retained for further evaluation.

To minimise the risk of excluding pertinent studies, the eligibility criteria were applied with caution and consistency. Full-text articles were subsequently assessed for methodological quality to ensure that only robust and reliable evidence was included in the review. All references retrieved from the databases were exported into EndNote X7 citation management software (Brahmi & Gall, 2006). Duplicate records were identified and removed during the merging process. Studies assessed to be of poor methodological quality were excluded from the final synthesis.

To ensure transparency and reproducibility, the study selection process was documented using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 checklist and the accompanying four-phase flow diagram (Page et al., 2021). This framework facilitated clear reporting of the identification, screening, eligibility, and inclusion stages.

## Data Extraction and Preparation

A structured paper-based data extraction format was employed to collect relevant information from each study. Summary statistics extracted included the mean and standard deviation (SD) for both intervention and control groups. In cases where SD values were not reported, standard error of the mean (SE or SEM) values were used to calculate SD using the formula:  $SD = SE \times \sqrt{n}$ , where  $n$  represents the number of participants.

For studies lacking both SD and SE values, Microsoft Excel 97–2003 was used to estimate SD. Input variables included p-values and group sample sizes, which were used to calculate t-values. These t-values, along with mean differences between groups, enabled the derivation of SE and subsequent SD values.

## Quality Appraisal

To ensure the methodological integrity of the included studies, the Critical Appraisal Skills Programme (CASP) checklist for Randomised Controlled Trials was employed

(CASP, 2014). This tool provides a structured framework for evaluating the trustworthiness, relevance, and rigour of healthcare research. Each study was assessed for clarity of aims, appropriateness of design, recruitment strategy, randomisation process, and the reliability of outcome measures. The CASP checklist also facilitated the identification of potential limitations in study conduct and reporting, thereby strengthening the overall validity of the systematic review.

## Risk of Bias Assessment

Risk of bias was evaluated using the Cochrane Collaboration's Risk of Bias Tool (CCRB), a widely accepted instrument for assessing methodological quality in randomised trials (Higgins & Green, 2011; 2024). The assessment was conducted using the Review Manager (RevMan) software, which enabled the systematic input of study characteristics and facilitated transparent documentation of bias judgments.

Each study was examined across six key domains of bias:

- Random sequence generation (selection bias): Evaluates whether the allocation sequence was adequately generated to prevent systematic differences between groups.
- Allocation concealment (selection bias): Assesses whether group assignment was hidden from participants and researchers to avoid baseline imbalances.
- Blinding of participants and personnel (performance bias): Determines whether care providers and participants were blinded to the intervention, reducing differential treatment effects.
- Blinding of outcome assessment (detection bias): Examines whether outcome evaluators were blinded, ensuring objectivity in data collection.
- Incomplete outcome data (attrition bias): Reviews the extent and handling of participant withdrawals, which may affect the reliability of results.
- Selective reporting (reporting bias): Identifies discrepancies between reported and unreported outcomes, which may distort the interpretation of findings.

This structured approach ensured that systematic differences between intervention and control groups were critically appraised, enhancing the transparency and reliability of the review's conclusions.



## Outcome Measures

The primary outcome measure was HbA1c, a continuous variable indicative of long-term glycaemic control. HbA1c values were extracted at baseline and post-intervention, typically expressed in either mmol/mol (range: 31–108) or percentage (range: 5–12%) (PitStop Diabetes, 2014; Shrier et al., 2016).

## Effect Measure and Evidence Grading

The effect measure used was Mean Difference (MD), which quantifies the absolute difference in mean HbA1c values between intervention and control groups, accounting for within-group variability. To assess the certainty of evidence and strength of recommendations, the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) framework was applied. The GRADEpro GDT software was used to generate evidence profiles and summary of findings tables (Schünemann et al., 2013).

## Data Analysis

Quantitative synthesis was conducted using Review Manager (RevMan) software version 5.3, developed by the Cochrane Collaboration (Cochrane Collaboration, 2014; Higgins & Thomas, 2024). The inverse variance method was selected for meta-analysis, appropriate for continuous outcome variables such as HbA1c. This approach allows for the weighting of studies based on the precision of their estimates, thereby enhancing the reliability of pooled results.

Following data extraction from the six included randomised controlled trials (see Table 8), the relevant statistics—mean values, standard deviations, and sample sizes—were entered into RevMan for analysis. The software generated key outputs including forest plots (blobbograms), funnel plots, Chi-squared statistics,  $I^2$  heterogeneity values, and overall effect estimates.

Given the continuous nature of the primary outcome measure (HbA1c), the fixed-effect model was applied. This model assumes that all included studies estimate a common true effect size, and is appropriate when heterogeneity is low or when the goal is to estimate the average effect under similar conditions (Borenstein, Hedges & Rothstein, 2007). A preliminary comparison with the random-effects model revealed minimal differences in

effect estimates, further justifying the use of the fixed-effect model in accordance with Cochrane Handbook recommendations (Higgins & Green, 2011; 2024).

The effect measure used was Mean Difference (MD), which quantifies the absolute difference in mean HbA1c values between intervention and control groups, accounting for variability within each study. This metric provides a direct and interpretable estimate of treatment impact.

To assess the certainty of evidence and the strength of the findings, the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) framework was employed. The GRADEpro GDT software facilitated the creation of evidence profiles and summary of findings tables, supporting transparent and structured evaluation of the quality of evidence across studies (Schünemann, Brożek, Guyatt & Oxman, 2013).

## RESULTS

### Study Selection Process

A systematic search of electronic databases and supplementary sources yielded a total of 1,267 records, comprising 1,261 entries from databases and 6 from other sources. Following the removal of 214 duplicate records, 1,053 unique citations remained for initial screening. Titles and abstracts were reviewed against the predefined eligibility criteria, resulting in the exclusion of 804 records deemed irrelevant or ineligible.

The full texts of the remaining 21 articles were retrieved and assessed for eligibility. Of these, 15 studies were excluded for the following reasons: inappropriate intervention ( $n = 4$ ), measurement of outcomes not aligned with the review objectives ( $n = 3$ ), inclusion of populations outside the target demographic ( $n = 2$ ), use of qualitative synthesis rather than quantitative analysis ( $n = 4$ ), and absence of extractable quantitative data ( $n = 2$ ). Ultimately, six RCTs, encompassing a total of 604 adult participants with type 2 diabetes mellitus, met the inclusion criteria and were incorporated into the final quantitative synthesis. The study selection process is illustrated in the PRISMA Flow Diagram (Figure 1) (see also Appendix 2).

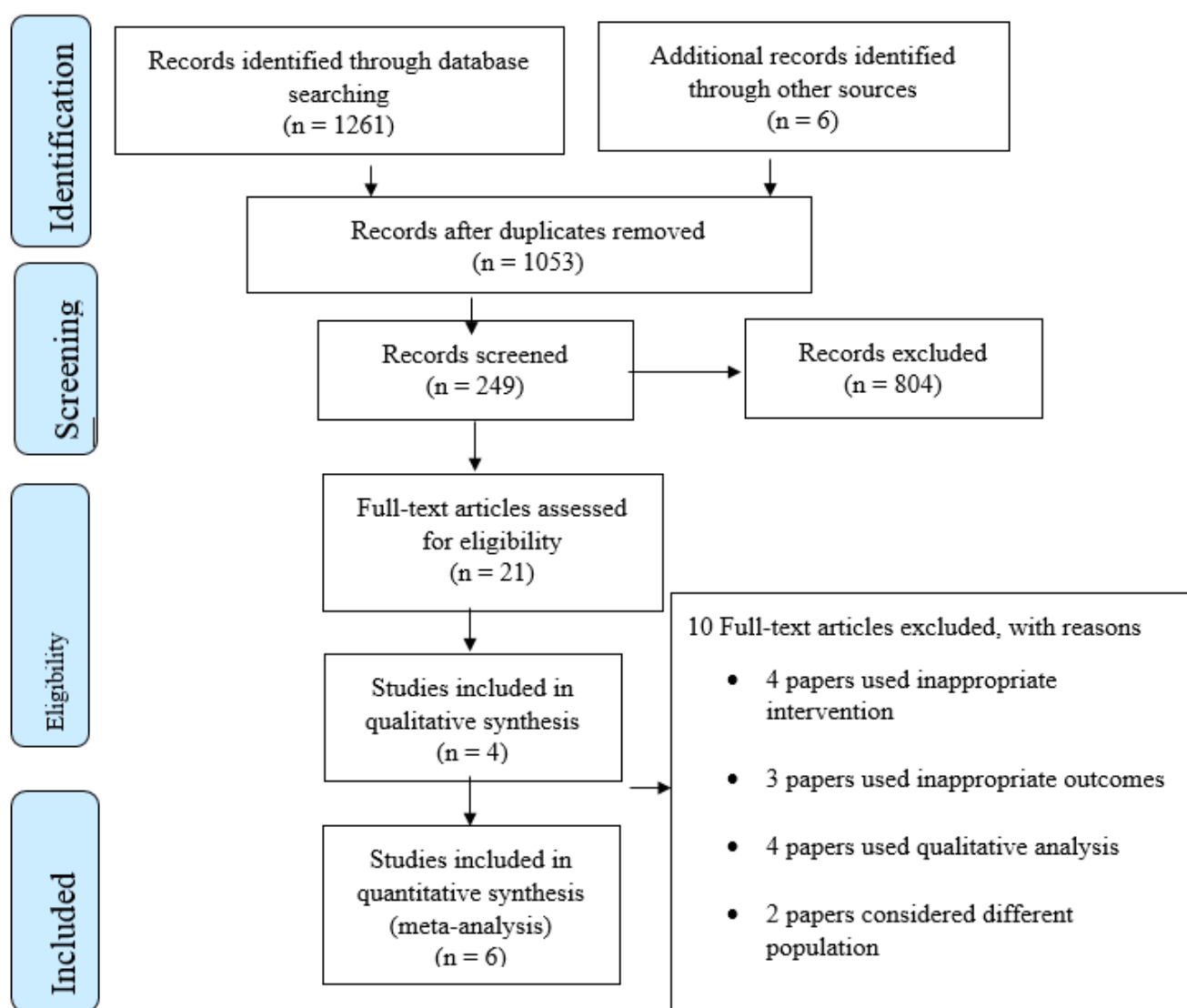


Figure 1: PRISMA Flow Diagram (Page et al., 2021)

### Characteristics of Included Studies

The meta-analysis incorporated six randomised controlled trials (RCTs), collectively involving 604 adult participants diagnosed with type 2 diabetes mellitus. A detailed summary of each study's characteristics—including participant demographics, intervention protocols, and reported outcomes—is presented in Appendix 1. While the specific dietary interventions varied across studies, all trials consistently compared a low glycaemic index (GI) or low-carbohydrate diet with a higher GI or high-carbohydrate control diet.

Intervention durations ranged from 4 to 52 weeks, allowing for both short- and longer-term assessments of dietary impact. Across all studies, the primary outcome measure was the change in HbA1c, a recognised biomarker of long-term glycaemic control. The majority of trials demonstrated

statistically significant reductions in HbA1c levels among participants receiving the low GI or low-carbohydrate intervention, indicating improved glycaemic outcomes relative to control groups.

### Data Extraction

The data extraction process, detailed in Appendix 3, was conducted using a structured paper-based format to ensure systematic collection of relevant information from each included study. Key variables extracted for meta-analysis included baseline and post-intervention HbA1c values, which served as the primary outcome measure for assessing glycaemic control.

### Quality Assessment

The Critical Appraisal Skills Programme (CASP) checklist (Appendix 4) was used to offer an appraisal of the methodological quality and statistical outcomes of the

studies included in this review. All studies scored “Y” across the CASP checklist items, suggesting strong adherence to critical appraisal standards—such as clarity of research aims, appropriateness of methodology, and validity of results. This consistency reinforces the reliability of the included evidence base.

Jenkins et al. (2011) and Tay et al. (2014) reported statistically significant mean differences in favour of the intervention, with p-values of 0.005 and 0.004 respectively. Westman et al. (2008) also showed a significant effect (MD = -0.6, p = 0.02), strengthening the case for dietary interventions in glycaemic control. Jenkins et al. (2012), however, had a p-value of 1.000, indicating no observable effect—an important nuance when interpreting pooled

results. Rizkalla et al. (2004) showed a large mean difference (-1.4), but with a wide confidence interval and a non-significant p-value (0.4542), suggesting variability or limited precision.

#### Data Analysis

Baseline HbA1c values in the intervention groups ranged from 6.3% to 7.8%, while those in the control groups ranged from 6.4% to 7.57%, indicating that the pooled study population exhibited moderately controlled type 2 diabetes at the outset. These values, summarised in Table 2, formed the foundation for the quantitative synthesis evaluating the effect of low glycaemic index (GI) diets on blood glucose regulation.

**Table 2: Study Outcome Data**

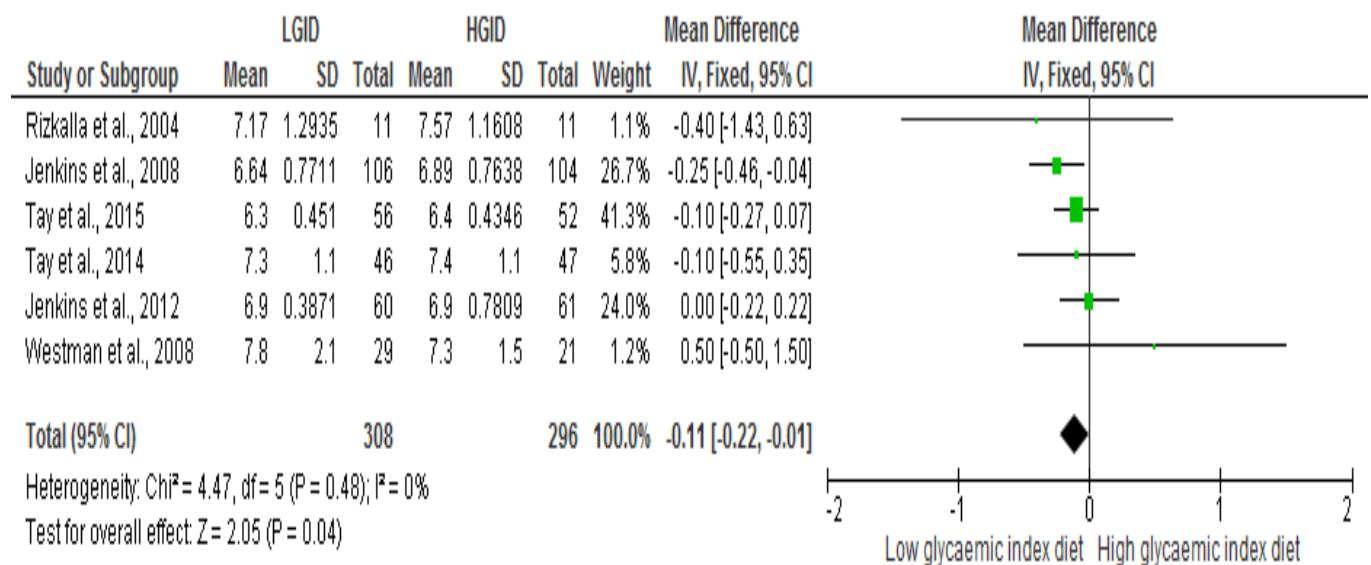
| Study          | Intervention (Low Glycaemic Index Diet) |                         |       | Control (High Glycaemic Index Diet) |                         |       |
|----------------|---|-------------------------|-------|-------------------------------------|-------------------------|-------|
|                | Mean                                    | Standard deviation (SD) | Total | Mean                                | Standard deviation (SD) | Total |
| Rizkalla, 2004 | 7.17                                    | 1.2935                  | 11    | 7.57                                | 1.1608                  | 11    |
| Jenkins, 2008  | 6.64                                    | 0.7711                  | 106   | 6.89                                | 0.7638                  | 104   |
| Tay, 2015      | 6.30                                    | 0.4510                  | 56    | 6.40                                | 0.4346                  | 52    |
| Tay, 2014      | 7.30                                    | 1.1000                  | 46    | 7.40                                | 1.1000                  | 47    |
| Jenkins, 2014  | 6.90                                    | 0.3871                  | 60    | 6.90                                | 0.7809                  | 61    |
| Westman, 2008  | 7.80                                    | 2.1000                  | 29    | 7.30                                | 1.5000                  | 21    |

Standard deviations across both intervention and control groups were generally consistent, suggesting comparable variability in glycaemic control within the study populations. These endpoint data were used to calculate the mean difference in HbA1c change between groups, enabling a robust comparison of treatment effects across trials.

Figure 2 presents the forest plot summarising the findings from all six included RCTs. Each study was categorised into either a low glycaemic index diet (LGID) intervention group

or a high glycaemic index diet (HGID) control group. The overall effect estimate derived from the meta-analysis favoured the LGID intervention, with the 95% confidence interval remaining entirely to one side of the line of no effect. This indicates a statistically significant difference between the intervention and control groups. The associated p-value (< 0.004) further supports the robustness of this finding, suggesting that low GI diets are more effective in improving glycaemic control among adults with type 2 diabetes mellitus.



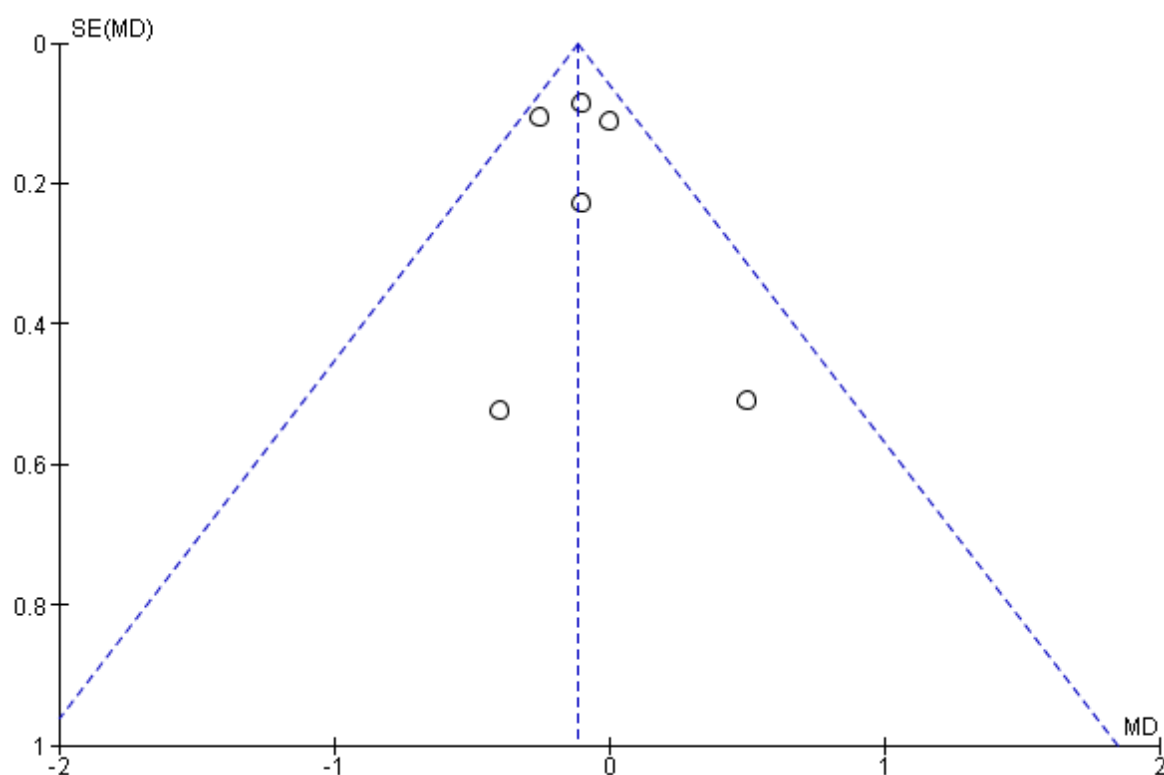


(Key: 0 – represents the study or subgroup)

**Figure 2: Forest Plot of Included Studies**

Publication bias was evaluated visually through a funnel plot, as presented in Figure 3. The plot illustrates a symmetrical distribution of effect estimates from the included studies around the pooled mean, indicating a balanced representation of study outcomes. The absence of

marked asymmetry suggests a low risk of publication bias, implying that the meta-analysis results are unlikely to be significantly influenced by the selective non-publication of smaller studies reporting null or negative findings.



(Key: 0 – represents the study or subgroup)

**Figure 3: Funnel Plot Assessing Publication Bias in Included Studies**

The overall quality of evidence for the primary outcome—change in HbA1c—was appraised using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) framework, as summarised in Table 3. The pooled analysis demonstrated that low glycaemic index (GI) diets were associated with a statistically significant reduction in HbA1c levels compared to high GI diets, yielding a mean difference (MD) of  $-0.11\%$  with a 95% confidence interval (CI) ranging from  $-0.22\%$  to  $-0.01\%$ .

Based on GRADE criteria, the certainty of this evidence was rated as moderate. Although the outcome was consistent and precise across studies, the rating was downgraded from high due to methodological limitations in two of the included trials. Specifically, concerns were raised regarding the absence of allocation concealment and lack of blinding of participants and personnel, which introduced potential risk of bias and reduced confidence in the internal validity of the findings.

**Table 3:** Summary of findings using the GRADE approach.

| <b>Low Glycaemic index diet compared to High glycaemic index diet for Type 2 diabetes mellitus</b>            |   |  |                          |                              |                                 |                           |
|---|---|--|--------------------------|------------------------------|---------------------------------|---------------------------|
| <b>Patient or population:</b> Type 2 diabetes mellitus  |   |  |                          |                              |                                 |                           |
| <b>Setting:</b> Home-based, Hospital or Community   |   |  |                          |                              |                                 |                           |
| <b>Intervention:</b> Low Glycaemic index diet   |   |  |                          |                              |                                 |                           |
| <b>Comparison:</b> High glycaemic index diet  |   |  |                          |                              |                                 |                           |
| Outcomes  | Anticipated absolute effects* (95% CI)                    |  | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments                  |
|   | Risk with High glycaemic index diet                       | Risk with Low Glycaemic index diet   |                          |                              |                                 |                           |
| Low blood glucose level assessed with: HbA1c Scale from: 5 to 12 (worse) follow up: range 8 weeks to 52 weeks | The mean low blood glucose level ranged from <b>6-7 %</b> | The mean low blood glucose level in the intervention group was 0.11 % lower (0.22 lower to 0.01 lower) | -                        | 604 (6 RCTs)                 | ⊕⊕⊕○<br>MODERATE <sup>a</sup>   | MD -0.11 (-0.22 to -0.01) |

\***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval; **MD:** Mean difference

**Table 3:** Summary of findings using the GRADE approach.**Low Glycaemic index diet compared to High glycaemic index diet for Type 2 diabetes mellitus****Patient or population:** Type 2 diabetes mellitus**Setting:** Home-based, Hospital or Community**Intervention:** Low Glycaemic index diet**Comparison:** High glycaemic index diet

| Outcomes | Anticipated absolute effects* (95% CI) |                                    | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|----------|--|------------------------------------|--------------------------|------------------------------|---------------------------------|----------|
|          | Risk with High glycaemic index diet    | Risk with Low Glycaemic index diet |                          |                              |                                 |          |

**GRADE Working Group grades of evidence****High quality:** We are very confident that the true effect lies close to that of the estimate of the effect**Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different**Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect**Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Table 4 presents a detailed breakdown of the GRADE assessment for the primary outcome—reduction in HbA1c. The evidence profile systematically evaluates the certainty of findings across five domains: risk of bias, inconsistency, indirectness, imprecision, and other considerations. For this outcome, no serious concerns were identified regarding inconsistency, indirectness, or imprecision, indicating that the results were consistent across studies, directly applicable to the target population, and sufficiently precise.

However, the overall quality of evidence was rated as moderate due to serious concerns related to risk of bias. As previously noted, two of the included studies lacked allocation concealment and blinding of participants and personnel, which may have introduced performance and selection bias. This downgrade provides a transparent rationale for the level of confidence assigned to the estimated treatment effect.

**Table 4: GRADE Evidence Profile for Included Studies**




































| Quality assessment  |              |              |               |              |             |                      | № of patients           |                          | Effect            |                   | Quality | Importance |
|---|--------------|--------------|---------------|--------------|-------------|----------------------|-------------------------|--------------------------|-------------------|-------------------|---------|------------|
| № of studies  | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Low Glycemic index diet | High glycemic index diet | Relative (95% CI) | Absolute (95% CI) |         |            |
| Low blood glucose level (follow up: range 8 weeks to 52 weeks; assessed with: HbA1c; Scale from: 5 to 12 (worse)) |              |              |               |              |             |                      |                         |                          |                   |                   |         |            |

| Quality assessment |                   |                      |               |              |             |                      | Nº of patients          |                          | Effect             |   | Quality              | Importance |
|--------------------|-------------------|----------------------|---------------|--------------|-------------|----------------------|-------------------------|--------------------------|--------------------|---|----------------------|------------|
| Nº of studies      | Study design      | Risk of bias         | Inconsistency | Indirectness | Imprecision | Other considerations | Low Glycemic index diet | High glycemic index diet | Relative (95 % CI) | Absolute (95% CI)                                 |                      |            |
| 6                  | randomised trials | serious <sup>a</sup> | not serious   | not serious  | not serious | none                 | 308                     | 296                      | -                  | MD <b>0.11 % lower</b> (0.22 lower to 0.01 lower) | ⊕⊕⊕<br>○<br>MODERATE |            |

CI: Confidence interval; MD: Mean difference; a: No allocation concealment, Study participants and dietitians were not blinded to treatment in study 2 and 5. Table 5 provides a detailed summary of the risk of bias assessments for each included study, based on the

Cochrane Collaboration’s criteria. A visual representation of these assessments is presented in Figure 4, illustrating the distribution of bias across key domains such as random sequence generation, allocation concealment, blinding, and outcome reporting.

Table 5: Risk of Bias Summary

|                      | Random sequence generation  | Allocation concealment  | Blinding of participants and personnel  | Blinding of outcome assessment  | Incomplete outcome data   | Selective reporting   | Other bias  |
|----------------------|---|---|---|---|---|---|---|
| Jenkins et al., 2008 |  |  |  |  |  |  |  |
| Jenkins et al, 2012  |  |  |  |  |  |  |  |
| Rizkalla et al, 2004 |  |  |  |  |  |  |  |
| Tay et al., 2014     |  |  |  |  |  |  |  |
| Tay et al., 2015     |  |  |  |  |  |  |  |








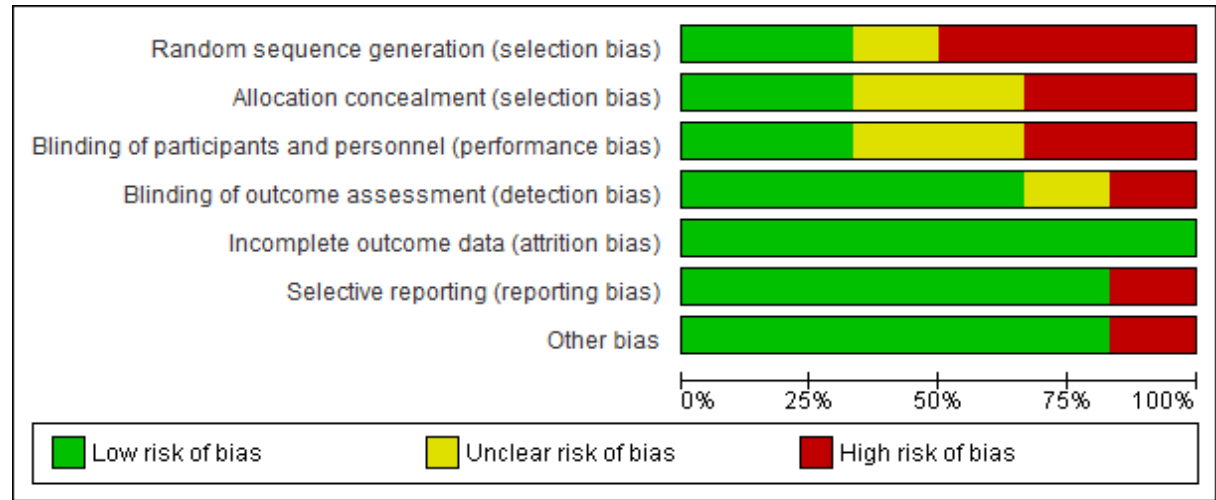
|                     |   |   |   |   |  |   |   |
|---------------------|---|---|---|---|--|---|---|
| Westman et al. 2008 |  |  |  |  |  |  |  |
|---------------------|---|---|---|---|--|---|---|



Figure 4: Graphical Summary of Risk of Bias



Summary of Findings

This systematic review and meta-analysis included six randomised controlled trials (RCTs) involving a total of 604 adult participants with type 2 diabetes mellitus. The primary outcome across all studies was the change in glycated haemoglobin (HbA1c), a key marker of long-term glycaemic control.

- Effect Estimate: The pooled analysis demonstrated a statistically significant reduction in HbA1c levels favouring low glycaemic index (GI) diets over high GI diets, with a mean difference (MD) of  $-0.11\%$  (95% CI:  $-0.22$  to  $-0.01$ ;  $p < 0.004$ ).
- GRADE Assessment: The overall certainty of evidence was rated as moderate, downgraded from high due to risk of bias in two studies—specifically, lack of allocation concealment and absence of blinding.
- Risk of Bias: Most studies were assessed as having low risk of bias across key domains, as summarised in Table 5 and illustrated in Figure 4.
- Publication Bias: Funnel plot analysis (Figure 3) revealed a symmetrical distribution of study estimates around the pooled effect size, suggesting a low likelihood of publication bias.

- Consistency: No serious concerns were identified regarding inconsistency, indirectness, or imprecision, supporting the reliability of the pooled effect.

DISCUSSION

This systematic review and meta-analysis aimed to evaluate the efficacy of a low GI diet compared to a high GI diet in lowering blood glucose levels, as measured by HbA1c in adults with type 2 diabetes. The synthesis of six RCTs, involving 604 participants, provides evidence that a low GI diet leads to a statistically significant, albeit modest, reduction in HbA1c levels (MD  $-0.11\%$ , 95% CI:  $-0.22$  to  $-0.01$ ). According to the GRADE framework, the overall quality of this evidence was rated as moderate. The primary finding of a beneficial effect of a low GI diet aligns with the physiological understanding that carbohydrates with a lower GI are digested and absorbed more slowly, leading to a more gradual rise in postprandial blood glucose and improved long-term glycaemic control (Brand-Miller et al., 2003). This conclusion is reinforced by more recent meta-analyses. For instance, Zafar et al. (2019) reported a larger HbA1c reduction (MD  $-0.31\%$ ) with low-GI diets, which also aligns with the findings of Peres et al. (2023). Similarly, Reynolds et al. (2020)



confirmed that low-GI and low-glycaemic load (GL) diets significantly improve glycaemic control, insulin sensitivity, and blood lipids in people with diabetes and prediabetes. The consistency of the direction of effect across all studies in the present review, despite variations in specific dietary protocols (e.g., low-GI legume diet, very low-carbohydrate diet), strengthens the conclusion that dietary patterns emphasising low-GI foods are effective for glycaemic control.

Importantly, the methodological quality of the included studies was evaluated using the CASP checklist. All six studies assessed met the criteria across all nine domains, reflecting strong internal validity and sound study design. Each trial clearly articulated its research objectives, applied appropriate methodologies, and reported findings transparently. This consistency in methodological rigour enhances confidence in the reliability of the evidence base and strengthens the credibility of the meta-analytic results. Moreover, these quality assessments lend support to the GRADE rating of moderate certainty, particularly in light of the variability in statistical significance and the presence of potential bias in a subset of studies.

The observed reduction in HbA1c, while small at the population level, remains clinically relevant. The American Diabetes Association (ADA) Standards of Care emphasise that even modest, sustained improvements in glycaemic control can significantly reduce the risk of microvascular complications over time (ADA, 2022). Furthermore, a recent network meta-analysis by Neuenschwander et al. (2019) positioned low-carbohydrate and low-GI diets among the most effective for improving HbA1c, supporting their inclusion in management strategies. The low statistical heterogeneity ( $I^2 = 0\%$ ) observed in our meta-analysis suggests that the studies were estimating a single common effect, increasing confidence in the robustness of the pooled result.

The validity of this research finding is further reinforced by a number of recent meta-analyses conducted since the completion of this literature search. These subsequent high-quality reviews have not only confirmed the effect but often reported larger magnitudes of benefit, underscoring the robustness of the dietary approach. For example, Zafar et al. (2019), in a comprehensive review of 54 studies (33 RCTs), found a more pronounced mean difference of  $-0.31\%$  (95% CI:  $-0.42$  to  $-0.19$ ). This larger effect size may be attributed to their inclusion of a greater number of studies and participants, providing more statistical power.

Beyond glycaemic control, the evidence base has evolved to highlight broader cardiometabolic benefits of low-GI diets. A landmark meta-analysis by Chiavaroli et al. (2021) concluded that low-GI and low-GL dietary patterns significantly improve LDL cholesterol, non-HDL cholesterol, and inflammatory markers like CRP. This positions the low-GI diet not merely as a tool for glucose management but as a comprehensive strategy to reduce cardiovascular risk in individuals with type 2 diabetes. The physiological rationale for these benefits is further supported by research into specific food groups. Reynolds et al. (2020) reinforced the importance of carbohydrate quality, showing that diets rich in dietary fibre and whole grains—key components of a low-GI diet—are consistently associated with better glycaemic control and reduced incidence of type 2 diabetes. This aligns with the findings of Jenkins et al. (2012), where a low-GI legume diet showed superior results, suggesting that the benefits are achievable through practical, food-based dietary patterns rather than meticulous GI calculation alone.

The findings of this review are consistent with earlier meta-analyses, such as the Cochrane review by Thomas and Elliott (2009), and update this evidence with studies published up to 2016. However, research in this field has continued to evolve. Recent guidelines, including those from the ADA (2024) and the European Association for the Study of Diabetes (EASD), now more explicitly recommend emphasising carbohydrate quality using GI and fibre as key metrics alongside quantity (Elsayed et al., 2024). The included trials were conducted primarily in developed nations within controlled hospital or research centre settings, with interventions delivered by healthcare professionals. While this context ensures high internal validity, it may limit generalisability to self-managed diets in diverse community or primary care settings, particularly in low- and middle-income countries (LMICs), where dietary resources, food availability, and cultural eating patterns differ significantly (Bennett et al., 2023).

Adverse effects reported in the included trials were minor, primarily gastrointestinal issues such as constipation—an expected side effect of dietary shifts, especially those higher in fibre or lower in certain carbohydrates. No serious adverse events were directly attributable to the low-GI intervention, suggesting it is a safe dietary approach. However, a limitation of the evidence base is that none of the included studies assessed patient-centred outcomes such as diabetes-related complications, mortality, or health-related quality of life. Cost-

effectiveness was also not evaluated. Emerging research, such as that by Chiavaroli et al. (2021), suggests that low-GI diets may reduce the risk of major cardiovascular events, highlighting the need for long-term trials powered for these critical endpoints.

The key strengths of this review include a comprehensive and systematic search strategy without language restrictions, a rigorous risk of bias assessment, and the application of the GRADE approach to evaluate the quality of evidence. The use of a pre-defined protocol and the focus on a clinically relevant outcome (HbA1c) further strengthen its validity. The CASP checklist results also reinforce the methodological soundness of the included studies, adding confidence to the overall conclusions.

Nonetheless, limitations remain. The relatively small number of studies available for inclusion constrained the ability to conduct more nuanced subgroup analyses. As with all dietary studies, the potential for performance bias exists. The varying durations of interventions (8 to 52 weeks) and the specific composition of the diets introduce clinical heterogeneity, although this was not reflected in the statistical heterogeneity. Since the search was conducted in 2016, newer RCTs and larger meta-analyses have been published. While they generally corroborate our findings, they often feature longer durations and a greater emphasis on whole-food, dietary-pattern approaches rather than isolated GI manipulation (Livesey et al., 2019).

Future research should aim to investigate these longer-term and broader outcomes. Studies with extended follow-up periods are needed to assess the impact of low-GI diets on diabetes-related complications, cardiovascular events, and quality of life. Moreover, practical implementation strategies—such as integrating low-GI foods into culturally appropriate meal plans—should be explored to enhance real-world applicability. High-quality trials are essential to establish the long-term benefits and feasibility of incorporating low-GI diets into routine diabetes care.

## CONCLUSION

This systematic review and meta-analysis provide moderate-quality evidence that low glycaemic index (GI) diets are effective in achieving a small but statistically significant improvement in glycaemic control in adults with type 2 diabetes, compared to high GI diets. The pooled findings, supported by rigorous methodological appraisal and consistent direction of effect across trials, reinforce the clinical relevance of dietary GI as a modifiable factor in diabetes management. While the reduction in HbA1c was

modest, it aligns with broader evidence suggesting that even small improvements can yield meaningful reductions in long-term complications.

This dietary strategy can be considered a safe and viable component of the overall management plan for type 2 diabetes. For clinicians and dietitians, these findings support the integration of low-GI food choices into patient education. Emphasising practical substitutions—such as legumes, whole oats, and certain fruits in place of high-GI options like white bread and potatoes—can help patients adopt sustainable dietary changes. For policymakers, the results underscore the importance of embedding evidence-based nutritional guidance into national diabetes management frameworks.

The review also highlights the evolving landscape of nutritional research, with recent meta-analyses and guidelines increasingly recognising the value of carbohydrate quality—particularly GI and dietary fibre—in managing both glycaemic and cardiometabolic outcomes. Although the included studies were generally well-conducted, limitations such as lack of blinding and short intervention durations underscore the need for future trials with longer follow-up, diverse populations, and patient-centred outcomes.

Future research should prioritise long-term studies conducted in real-world settings to assess the sustainability of low-GI diets and their impact on hard clinical endpoints such as diabetes-related complications, cardiovascular events, and quality of life. High-quality trials are essential to establish the long-term benefits and feasibility of incorporating low-GI diets into routine diabetes care across diverse populations and healthcare systems.

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The author declares that he has no known competing financial interests or personal relationships that could

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## APPENDICES

### Appendix 1: Characteristics of included studies

| Study/Title   | Participants   | Intervention vs. comparator   | Outcome  |
|---|--|---|--|
| Jenkins et al. (2008)<br><br>Effect of a low glycemic index or a high cereal fiber diet on type 2 diabetes: A randomized controlled trial.  | A total number of 210 study participants were recruited. 106 participants were allocated to the intervention group and 104 participants were allocated to the control group.                         | Low glycaemic index diet intervention versus high cereal fiber diet for 6 months.   | HbA1c decreased by -0.18% absolute HbA1c units (95% confidence interval [CI], -0.29% to -0.07%) in the high-cereal fibre diet compared to -0.50% absolute HbA1c units (95% CI, -0.61% to -0.39%) in the low-glycemic index diet ( $P_{.001}$ ).  |
| Jenkins et al. (2012)<br><br>Effect of legumes as part of a low glycaemic index diet on glycaemic control and cardiovascular risk factors in type 2 diabetes Mellitus. A randomized controlled trial. | A total of 121 study participants were recruited for the study. 58 participants were randomized to receive the intervention diet and 56 participants were randomized to receive the comparator diet. | High wheat fiber diet versus low glycaemic legume diet.   | The low-GI legume diet reduced HbA1c values by -0.5% (95% CI, -0.6% to -0.4%) and the high wheat fibre diet reduced HbA1c values by -0.3% (95% CI, -0.4% to -0.2%). The relative reduction in HbA1c values after the low-GI legume diet was greater than after the high wheat fibre diet by -0.2% (95% CI, -0.3% to -0.1%; $P_{.001}$ ). |
| Tay et al., (2014)<br><br>A very low carbohydrate low saturated fat diet for type 2 diabetes management: A randomized trial.  | 115 obese adults with type 2 diabetes mellitus were randomized into 2 groups. 46 obese adults completed the intervention diet while 47 obese adults completed the comparator diet.                   | Very low carbohydrate, high unsaturated/ low saturated fat diet: hypocaloric LC diet (14% carbohydrate [50g/day], 28% protein, and 58% fat [10% saturated]) versus high unrefined carbohydrate, low fat diet: energy-matched HC diet (53% carbohydrate, 17% protein, and 30% fat [ $<10\%$ saturated fat]). | Both groups achieved similar completion rates fasting glucose was $(-1.4 \pm 2.3 \text{ mmol/L})$ . LC diet reduced HbA1c $(-2.6 \pm 1.0\% [-2.8 \pm 10.9 \text{ mmol/mol}] \text{ vs. } -1.9 \pm 1.2\% [-20.8 \pm 13.1 \text{ mmol/mol}]; p= 0.007)$ .  |

| Study/Title  | Participants   | Intervention vs. comparator  | Outcome  |
|--|--|--|--|
| Tay et al. (2015)<br><br>Comparison of low and high carbohydrates diets for type 2 diabetes management: a randomized trial.  | 115 obese adults with type 2 diabetes mellitus were recruited for the study. 58 participants were assigned to the intervention group and 57 participants were assigned to the control group.                             | Very low carbohydrate, high unsaturated fat (LC) diet versus high carbohydrate, low fat (HC) diet.   | There was substantial reduction in HbA1c and fasting glucose for both diets. The low glycaemic index diet received the greater improvement. HbA1c [LC diet: 21.0% (21.2%, 20.7%); HC diet: 21.0% (21.3%, 20.8%)], fasting glucose [LC diet: 20.7 mmol/L (21.3, 20.1 mmol/L); |
| Westman et al., (2008)<br><br>The effect of a low carbohydrate, ketogenic diet versus a low glycaemic index diet on glycemic control in type 2 diabetes mellitus.                                    | 84 community volunteers with obesity and type 2 diabetes mellitus were randomized into 2 groups. At the end of the study, 29 volunteers completed the intervention diet and 21 volunteers completed the comparator diet. | Low glycemic, reduced calorie diet (500 kcal/day deficit from weight maintenance diet; LGID) versus low carbohydrate ketogenic diet (< 20g of carbohydrate daily; LCKD). | The was a significant improvement in haemoglobin A1c, fasting glucose, fasting insulin, and weight loss for both groups. The low carbohydrate ketogenic diet group had greater improvements in haemoglobin A1c (-1.5% vs. -0.5%, p = 0.03).                                  |
| Rizkalla et al. (2004)<br><br>Improved plasma glucose control, whole body glucose utilization and lipid profile on a low glycaemic index diet in type 2 diabetic men: A randomized controlled trial. | 12 type 2 diabetic men were recruited for a 4-week intervention.   | Low glycaemic index carbohydrate diet or high glycaemic carbohydrate diet separated by a 4-week washout interval in a crossover design.                                  | After 4 weeks of low glycaemic index diet versus high glycaemic index diet, the low glycaemic index diet induced an improvement in fasting blood glucose (p < 0.01).   |

### Appendix 2: Initial Study Selection Process

| <b>Database Search</b>                          | <b>Search terms (Keywords)</b>   | <b>Date assessed (2016)</b>                              | <b>Number of studies identified with liberal screening of database</b> | <b>Excluded due to non-relevance to inclusion criteria and research question.</b> | <b>Studies for more detailed evaluation</b> | <b>Limit to the number of years and language restrictions<br/><br/>(January, 2004 to September, 2016)</b> |
|---|--|--|--|---|---|---|
| CINAHL plus with full text                      | “Type 2 diabetes mellitus” AND low glyc* index diet  | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 248  | 150   | 98  | Limit to 12 years, no language restrictions.  |
| CINAHL plus with full text                      | “Type 2 diabetes” AND<br><br>“low glyc* index diet” AND “high glyc* index diet” AND “blood glucose levels”     | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 31   | 18  | 13  | Limit to 12 years, no language restrictions.  |
| CINAHL plus with full text                      | “Type 2 diabetes in adults” AND “Low glyc* “Index diet” AND “blood glucose” AND “Randomised controlled trials” | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 7  | 6   | 1   | Limit to 12 years, no language restrictions.  |
| Medline   | “Type 2 diabetes mellitus” AND “low glycaemic index diet”  | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 267  | 265   | 2   | Limit to 12 years, no language restrictions.  |
| Cochrane Library, Issue 9 of 12, September 2016 | “Type 2 diabetes mellitus” AND low glyc* index diet  | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 334  | 228   | 106   | Limit to 12 years, no language restrictions.  |

| <b>Database Search</b>                           | <b>Search terms (Keywords)</b>   | <b>Date assessed (2016)</b>                              | <b>Number of studies identified with liberal screening of database</b> | <b>Excluded due to non-relevance to inclusion criteria and research question.</b> | <b>Studies for more detailed evaluation</b> | <b>Limit to the number of years and language restrictions<br/><br/>(January, 2004 to September, 2016)</b> |
|--|--|--|--|---|---|---|
| Cochrane Library, Issue 9 of 12, September, 2016 | “Type 2 diabetes in adults” AND “Low glyc* index diet” AND “blood glucose” AND “Randomised controlled trials”  | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 2  | 0   | 1   | Limit to 12 years, no language restrictions.  |
| Embase   | “Type 2 diabetes mellitus” AND low glyc* index diet  | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 366  | 255   | 1   | Limit to 12 years, no language restrictions.  |
| Embase   | “Type 2 diabetes in adults” AND “Low glyc* “Index diet” AND “blood glucose” AND “Randomised controlled trials” | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 1  | 0   | 1   | Limit to 12 years, no language restrictions.  |
| Google scholar                                   | “Type 2 diabetes in adults” AND “Low glyc* index diet” AND “blood glucose” AND “Randomised controlled trials”  | 12 <sup>th</sup> September to 14 <sup>th</sup> September | 4  | 3   | 1   | Limit to 12 years, no language restrictions.  |
| Database of Abstract of Reviews of               | “Type 2 diabetes in adults” AND  | 12 <sup>th</sup> September                               | 0  | 0   | 0   | Limit to 12 years, no   |



| Database Search | Search terms (Keywords)  | Date assessed (2016)          | Number of studies identified with liberal screening of database | Excluded due to non-relevance to inclusion criteria and research question. | Studies for more detailed evaluation | Limit to the number of years and language restrictions<br><br>(January, 2004 to September, 2016) |
|-----------------|--|-------------------------------|---|--|--------------------------------------|--|
| Effects (DARE), | “Low glyc* index diet”<br>AND “blood glucose”<br>AND<br>“Randomised controlled trials” | to 14 <sup>th</sup> September |   |  |                                      | language restrictions.   |
| Total           |  |                               | 1261  | 926  | 223                                  |  |

Appendix 3: Data Extraction Table

| 1 <sup>st</sup> Author (year of publication) | When trial was conducted              | Study design                      | Country and trial setting   | Comparison population/control                       | Study size   | Patient characteristics  | Follow-up period    | Outcome measure                                   | Commercial research support   |
|--|---------------------------------------|-----------------------------------|---|---|--|--|---------------------|---|---|
| Jenkins et al., 2008                         | Between September, 2004 and May, 2007 | Randomised, parallel study design | Toronto, Ontario Canada.<br><br>In the Risk Factor Modification Centre, St. Michael's Hospital. | Low glycaemic index diet vs. high cereal fibre diet | Total 210<br><br>Low glycaemic index diet (106)<br><br>High cereal fibre (104) | 210 type 2 diabetic mellitus patients being treated with anti-hyperglycaemic medications | 6 months (24 weeks) | Glycaemic control and cardiovascular risk factors | Canadian Institute of Health Research, Canada Research Chair endowment of the Federal government of Canada, and |

| 1 <sup>st</sup> Author (year of publication) | When trial was conducted               | Study design                     | Country and trial setting   | Comparison population/ control  | Study size  | Patient characteristics                        | Follow-up period     | Outcome measure   | Commercial research support                                    |
|--|--|----------------------------------|---|---|---|--|----------------------|---|--|
|  |  |                                  |   |   |   |  |                      |   | Barilla (Italy)  |
| Jenkins et al., 2012                         | February, 2010 to August, 2011         | Randomised parallel study design | Toronto, Ontario Canada.<br><br>In a research centre  | Low glycaemic index legume diet vs. high wheat fibre diet                                 | Total 210<br><br>Low glycaemic index legume diet (60)<br><br>High wheat fibre diet (61)                                       | 121 participants with type 2 diabetes mellitus | 3 months (12 weeks)  | Change in haemoglobin A1c (HbA1c) and values of calculated coronary heart disease (CHD) risk score. | ABIP through the PUREN et and the Saskatchewan pulse Growers . |
| Tay et al., 2015                             | Between May, 2012 and September, 2013. | Randomised controlled trial      | Adelaide, Australia.<br><br>In the Commonwealth, Scientific and Industrial Research Organisation (CSIRO) Clinical Research Unit | Very low carbohydrate, high unsaturated fat (LC) vs. high carbohydrate, low fat (HC) diet | Total 115<br><br>Very low carbohydrate, high unsaturated fat (LC) diet (58)<br><br>High carbohydrate, low fat (HC) diet (57). | 115 obese adults with type 2 diabetes          | 12 months (52 weeks) | Glycemic control<br><br>Fasting glucose<br><br>Glycemic variability                                 | Not stated   |

| 1 <sup>st</sup> Author (year of publication) | When trial was conducted              | Study design                | Country and trial setting   | Comparison population/ control   | Study size  | Patient characteristics                                  | Follow-up period    | Outcome measure  | Commercial research support   |
|--|---------------------------------------|-----------------------------|---|--|---|--|---------------------|--|---|
| Westman et al., 2008                         | 2008                                  | Randomised controlled trial | Durham, USA.<br><br>In an Outpatient research clinic.   | Low carbohydrate, ketogenic diet vs. low glycaemic, reduced calorie diet   | Total 50 out of 84 recruited participants completed the trial.<br><br>Low carbohydrate, ketogenic diet (21)<br><br>Low glycaemic, reduced calorie diet (29) | 84 community volunteers with obesity and type 2 diabetes | 6 months (24 weeks) | Glycaemic control  | Robert C. Atkins Foundation.<br><br>VA Health Research career development Award.  |
| Tay et al., 2014                             | Between May, 2012 and February, 2013. | Randomised trial            | Australia, Adelaide.<br><br>In the Commonwealth, Scientific and Industrial Research Organisation (CSIRO) Clinical Research Unit | Very low carbohydrate, high unsaturated/ low saturated fat diet (LC) vs. high unrefined carbohydrate, low fat diet (HC). | Total 115<br><br>LC diet (58).<br><br>HC diet (57).   | 115 obese adults with type 2 diabetes mellitus.          | 6 months (24 weeks) | Glycaemic control and cardiovascular disease (CVD) risk factors. | National health and Medical Research Council project grant.<br><br>Agency for Science, Technology and Research (A*STAR) |

| 1 <sup>st</sup> Author (year of publication) | When trial was conducted | Study design                | Country and trial setting             | Comparison population/control                | Study size  | Patient characteristics | Follow-up period  | Outcome measure   | Commercial research support   |
|--|--------------------------|-----------------------------|---------------------------------------|--|---|-------------------------|---|---|---|
| Rizkalla et al., 2004                        | 2004                     | Randomised controlled trial | Paris, France.<br>Hotel-Dieu Hospital | Low glycaemic index vs. high glycaemic index | Total 12<br><br>Low glycaemic index (12)<br><br>High glycaemic index (12) | 12 diabetic volunteers  | 4 weeks with 4 weeks' washout period between interventions. | Glycated haemoglobin<br><br>Plasma glucose,<br><br>Plasma insulin,<br><br>Plasma lipids,<br><br>Body weight | INSERM,<br><br>Pierre and Marie Curie University, Danone Vitapole, Nestle France<br><br>Association Benjamin Delessert and Association of Young Diabetic Individuals, France. |

#### Appendix 4: CASP Checklist

| S/N | Author               | 1 | 2 | 3 | 4 | 5 | 6 | 7   | 8   | 9 | 10 | 11 |
|-----|----------------------|---|---|---|---|---|---|---|---|---|----|----|
| 1   | Jenkins et al., 2008 | Y | Y | N | Y | Y | Y | Glycemic control and cardiovascular risk factors  | MD = -2.5<br><br>95% CI (-0.46, -0.04)<br><br><i>P</i> value = 0.0192 | Y | Y  | Y  |
| 2   | Jenkins et al. 2012  | Y | Y | N | Y | Y | Y | Change in haemoglobin A1c (HbA1c) and values of calculated coronary heart disease (CHD) risk score. | MD = 0.00<br><br>95% CI (-0.22, 0.22)<br><br><i>P</i> value = 1.000   | Y | Y  | Y  |
| 3   | Tay et al. 2015      | Y | Y | Y | Y | Y | Y | Glycemic control  | MD = -0.10  | Y | Y  | Y  |

| S/N | Author               | 1 | 2 | 3 | 4 | 5 | 6 | 7   | 8   | 9 | 10 | 11 |
|-----|----------------------|---|---|---|---|---|---|---|---|---|----|----|
|     |                      |   |   |   |   |   |   | Fasting glucose<br><br>Glycemic variability   | 95% CI (-0.27, 0.07)<br><br><i>P</i> value = 0.2440                   |   |    |    |
| 4   | Westman et al. 2008  | Y | Y | Y | Y | Y | Y | Glycemic control  | MD = 0.50<br><br>95% CI (-0.50, 1.50)<br><br><i>P</i> value = 0.3563  | Y |    |    |
| 5   | Tay et al. 2014      | Y | Y | Y | Y | Y | Y | Glycaemic control and cardiovascular disease (CVD) risk factors.  | MD = -0.10<br><br>95% CI (-0.55, 0.35)<br><br><i>P</i> value = 0.6622 | Y | Y  | Y  |
| 6   | Rizkalla et al. 2004 | Y | Y | Y | N | Y | Y | Glycated haemoglobin<br><br>Plasma glucose,<br><br>Plasma insulin,<br><br>Plasma lipids,<br><br>Body weight | MD = -0.40<br><br>95% CI (-1.43, 0.63)<br><br><i>P</i> value = 0.4542 | Y | Y  | Y  |