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## Review

# Effect of different dietary approaches compared with a regular diet on systolic and diastolic blood pressure in patients with type 2 diabetes: A systematic review and meta-analysis



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## ABSTRACT

**Aims:** We aimed to investigate the effect of different dietary approaches on systolic and diastolic blood pressure (SBP and DBP) in Type II diabetes (T2D).

**Methods:** A systematic search was performed in Web of Science, PubMed, Scopus and Cochrane library without any language and time restriction up to December 2018, to retrieve the randomized controlled trials (RCTs) which examined the effects of different dietary approaches on SBP and DBP in T2D patients. Meta-analyses were carried out using a random effects model. I<sup>2</sup> index was used to evaluate the heterogeneity.

**Results:** Twenty four RCTs with 1130 patients were eligible. The dietary modifications were more effective in reducing both SBP and DBP vs. control diet. The Low-sodium, High-fiber, DASH, Low-fat, Low-protein and Vegan dietary approach were significantly more effective in reducing SBP compared to a control diet. The High-fiber, Low-fat, Low-protein and Vegan diet were significantly more effective in reducing DBP. The Low-sodium and High fiber diets had the greatest lowering effect on SBP and DBP in T2D patients.

**Conclusions:** Adopting healthful dietary modifications were more effective in reducing both SBP and DBP vs. control. The High-fiber and Low-sodium diets had the greatest lowering effect on SBP and DBP in T2D.

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## 1. Introduction

Type II diabetes (T2D) is associated with an increased risk of macrovascular disorders, like myocardial infarction and stroke [1]. This disease is now the main cause of blindness in developed countries, and is the main cause of kidney diseases through its microvascular complications [2,3]. Levels of blood pressure (BP) in T2D patients are on average higher, which is the major cause of cardiovascular diseases in these patients [4]. Cardiovascular diseases have a main role in the morbidity and mortality of T2D patients [5]. Several pathophysiological mechanisms have been proposed to illustrate the relationship between hypertension and diabetes. It has been reported that adrenergic system is incriminated in the pathogenesis of hypertension in diabetes [6,7]. As a result of the high prevalence of hypertension in patients with diabetes and its role as the major risk factor of diabetes, substantial studies have investigated the clinical management and treatment of hypertension in these patients.

Evidence suggest the role of dietary modifications in prevention and management of hypertension. According to the latest American Heart Association guidelines, hypertensive and pre-hypertensive patients should follow dietary recommendations such as sodium reduction, and increasing intake of vegetables and fresh fruits [8]. Although various dietary recommendation have been provided so far, these recommendations for prevention and management of high BP are not yet comprehensive [9]. A recent systematic review and meta-analysis indicated that the DASH diet might be the most effective dietary approach to reduce BP among pre-hypertensive and hypertensive patients [10]. Considering that high BP is common in T2D patients and dietary modifications are effective in management of the high BP, one of the most important questions to ask is which diet is effective in reducing BP in T2D patients. Therefore, we carried out a systematic review and meta-analysis of RCTs to assess the effect of

different dietary approaches on systolic blood pressure (SBP) and diastolic blood pressure (DBP) in T2D patients.

## 2. Methods

We performed this systematic review and meta-analysis according to the guidelines of the 2009 preferred reporting items for systematic reviews and meta-analysis (PRISMA) statement [11].

### 2.1. Data sources and search strategies

A comprehensive literature search of six databases, including PubMed, the Cochrane Library, Web of Science and SCOPUS was conducted using the keywords: “Diabetes Mellitus” OR “Noninsulin-Dependent Diabetes Mellitus” OR “Type 2 Diabetes Mellitus” in combination with the keywords: “Carbohydrate Restricted Diet” OR “Low Carbohydrate Diet” OR “Mediterranean Diet” OR “Fat Restricted Diet” OR “Low Fat Diet” OR “Fat Free Diet” OR “Vegetarian Diet” OR “Ketogenic Diet” OR “Protein Restricted diet” OR “Low Protein Diet” OR “Protein Free Diet” OR “Diabetic Diet”, AND “Blood Pressure” OR “Diastolic Pressure” OR “Pulse Pressure” OR “Systolic Pressure”, for studies in all languages published up to December, 2, 2018. The complete search strategy is presented in [supplemental file 1](#).

### 2.2. Study selection

All the potentially relevant studies obtained from the databases were reviewed by two investigators (F.F. and P.K.). The titles and abstracts of retrieved publications were initially screened for potentially eligible studies, which were subsequently evaluated by full-text review. Randomized clinical tri-

als (RCTs) were included if the study population was adults (mean age  $\geq 18$  years), and if they presented results on the effect of the different dietary approaches with any duration of treatment on systolic or diastolic blood pressure vs. a control diet, advice only, or standard follow-up in T2D patients. Animal-based studies, reviews, posters, and letters to the editor were excluded. The initial search was supplemented by checking the reference lists of the retrieved articles to identify missed studies. Disagreements about the eligibility of any article were solved by discussing with a third author (A.A.).

### 2.3. Data extraction and quality assessment

Data from eligible studies were extracted by two investigators (P.K. and F.F.) using an Excel form. The following data were extracted from each eligible study: first author, publication year, study location, dietary approaches, study design, sample size, systolic and diastolic blood pressure, age, body mass index (BMI) and sex ratio. When the data were insufficient for a meta-analysis, we contacted the authors directly to obtain the data.

For assessing risk of bias the Cochrane Collaboration's tool was used [12]. This tool has nine items and each item were divided into six domains of bias with three rating categories:

(1) low risk of bias (alter the results significantly); (2) unclear risk of bias (raises some doubt about the results); and (3) high risk (seriously weakens confidence in the results). All selected articles were scored by 2 authors (AA and RC). Disagreement between the authors was resolved by a third assessor (EF).

### 2.4. Data synthesis and statistical analysis

Mean and standard deviation (SD) of related variables at baseline and post intervention was used to compare changes between control and intervention groups. When S.D of change was not reported, it was calculated using following formula:  $s.d. = \text{square root} [(s.d. \text{ pre-intervention})^2 + (s.d. \text{ post-intervention})^2 - (2R \times s.d. \text{ pre-intervention} \times s.d. \text{ post-intervention})]$ . A correlation coefficient of 0.8 was assumed as R-value of the above-mentioned formula. Standard error (SE) was converted to SD by multiplying SE with  $\sqrt{n}$ , where n is the sample size of each group. If the variables were reported in median and range (or 95% confidence interval (CI)), mean and SD were estimated according to the method by Hozo et al., [13]. When the variables reported in the graphic form, the software GetData Graph Digitizer 2.24 [14] was used to digitize and extract the data. Either fixed or random effects model was used to calculate pooled effect size of outcome

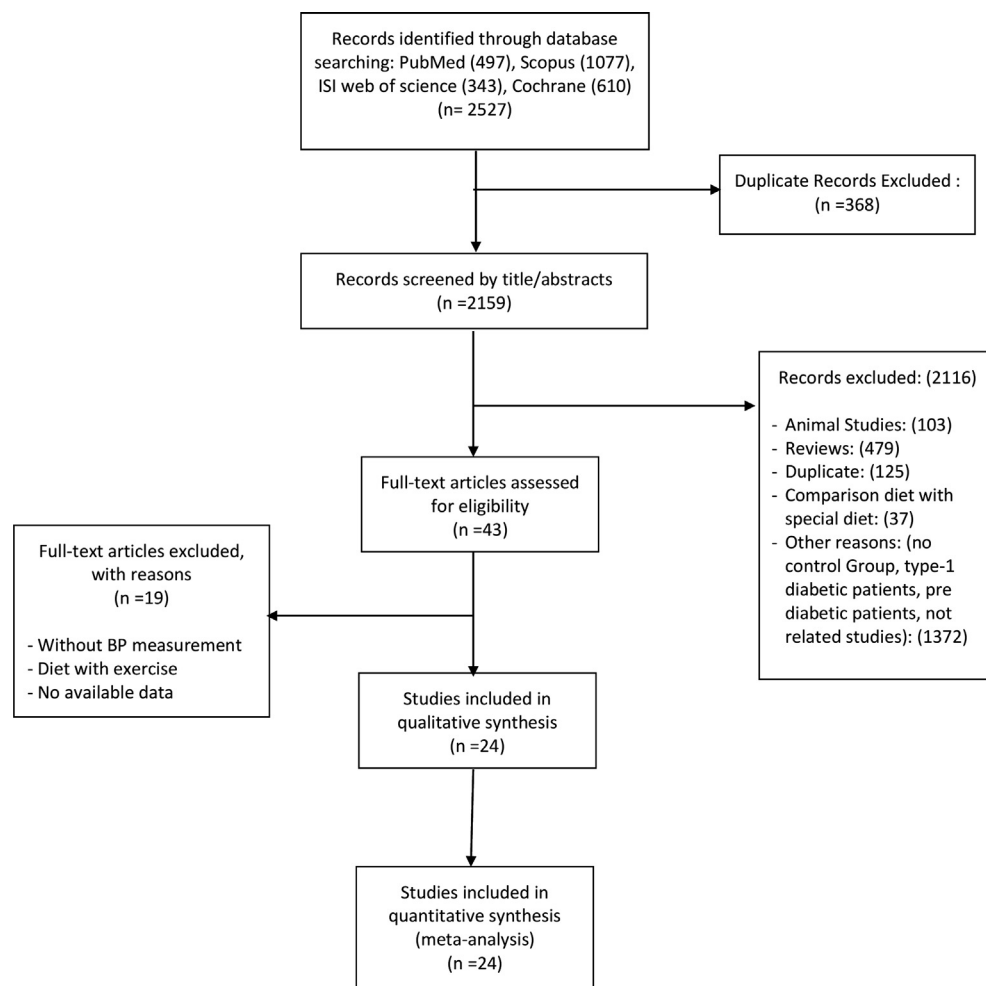


Fig. 1 – Flow diagram of the literature search.

data. Publication bias was assessed using visual assessment of funnel plots, Begg test and Egger's regression asymmetry test. We performed the sensitivity analysis by conducting one-study remove (leave-one-out) approach, to estimate the impact of each trial on the pooled effect size. Between-study heterogeneity was examined using Q test and I-square ( $I^2$ ) test [15]. All analyses conducted using STATA v.12 (Stata Corporation, College Station, TX, USA).

### 3. Results

#### 3.1. Study selection

The first step of the search yielded 497, 610, 343 and 1077 citations in PubMed, Cochrane Library, Web of Science, and SCOPUS, respectively (Fig. 1). Of these, 368 articles were excluded due to duplication. The titles and abstracts of 2159 articles were reviewed. Forty three studies were identified for full-text review. Of these, 19 studies were excluded for the following reasons: without BP measurement, diet with exercise, and no available data. Finally, 24 articles were included in the meta-analysis.

#### 3.2. Study characteristics

The included studies were published between 1984 and 2019, with a total sample size of 1130 participants in the intervention arm and 1247 participants in the control arm. All 24 studies were double blinded and placebo-controlled studies. The definition of the different intervention diets was heterogeneous for the prescribed diets (ad-libitum, iso-caloric, hypocaloric). The intervention durations were from 2 to 154 weeks. Age range of the participants was 29.4 to 72 years old. Three studies were conducted in Iran [16–18], 1 in Japan [19], 7 in USA [20–26], 3 in United Kingdom [27–29], 2 in Italy [30,31], 2 in Korea [32,33] and 1 in each of the countries of Netherland [34], Mexico [35], Malaysia [36], Sweden [37], Israel [38] and Greece [39]. Twenty two studies were parallel in design, and two studies were crossover. Twenty two studies were conducted on both genders, 1 study enrolled females [17], and 1 study enrolled males [21]. Number of the studies which were included to assess the effect of a particular dietary approach is as follows: vegan ( $n = 4$ ), Low-fat ( $n = 4$ ), DASH ( $n = 3$ ), Low-sodium ( $n = 2$ ), High-fiber ( $n = 3$ ), Low-protein ( $n = 3$ ), High-protein ( $n = 3$ ), Low-carbohydrate ( $n = 2$ ), Low-glycemic index (GI) ( $n = 2$ ), Paleolithic ( $n = 2$ ), Mediterranean ( $n = 1$ ) and Korean traditional diet ( $n = 1$ ). Characteristics of the included studies are summarized in Table 1.

#### 3.3. Assessment of risk of bias

The RCTs risk of bias is indicated in Table 2. The assessors agreed on 61 of the 77 items, resulting in 79% agreement rate. After discussion and consulting with a third assessor (EF), 100% agreement was reached. Three studies [17,24,37] had the lowest risk of bias and reached the highest score (6 out of 7). Overall, of 24 studies, 16 studies had a low risk of bias and reached a score of  $\geq 4$  out of 7. Lack of blinding of partic-

ipants and personnel was present in all except 1 study [17]. More details are shown in the Table 2.

#### 3.4. Publication bias and sensitivity analyses

The evaluation of publication bias using funnel plots demonstrated no evidence of publication bias within the studies (Supplementary Fig. 1). Furthermore, based on both the Egger test and the Begg test, there were no statistical evidence of publication bias among the included studies in the overall analysis (SBP:  $p = 0.29$ ,  $p = 75$ ; DBP:  $p = 0.15$ ,  $p = 83$ ; respectively). To evaluate the strength of our results, we made a sensitivity analysis. However, removing each individual study by sensitivity analysis did not change the pooled effect size (Supplementary Fig. 2).

#### 3.5. Meta-Analysis

Results of the Figs. 2 and 3 show that the dietary modifications were more effective in reducing both SBP and DBP vs. control diet (pooled weighted mean differences (WMD) with 95% CI:  $-4.26$  ( $-5.55$ ,  $-2.96$ );  $-2.44$  ( $-3.66$ ,  $-1.22$ ); respectively). Following dietary approaches were more effective in reducing SBP than control diet: High-fiber (WMD:  $-9.08$  ( $-13.46$  to  $-4.71$ )), DASH (WMD:  $-6.19$  ( $-9.43$ ,  $-2.94$ ), High-protein (WMD:  $-3.26$  ( $-4.19$ ,  $-2.32$ ), Low-fat (WMD:  $-5.72$  ( $-6.09$ ,  $-5.35$ )), Low-sodium (WMD:  $-10.84$  ( $-14.65$ ,  $-7.08$ )), Low-protein ( $-3.26$  ( $-5.38$ ,  $-1.15$ )) and Vegan (WMD:  $-3.05$  ( $-4.95$ ,  $-1.15$ )) (Supplementary Fig. 3). Whereas, Low-carbohydrate, Low-GI/GL and Paleolithic diets had no significant effect on SBP (Supplementary Fig. 3). According to the results, the following dietary approaches were more effective in reducing DBP in comparison with control diet: High-fiber (WMD:  $-7.28$  ( $-9.28$ ,  $-5.29$ )), Low-fat (WMD:  $-5.53$  ( $-5.75$ ,  $-5.3$ )), Low-protein (WMD:  $-5.02$  ( $-9.89$ ,  $-0.15$ )) and Vegan diet (WMD:  $-3.1$  ( $-4.48$ ,  $-1.71$ )) (Supplementary Fig. 4). Dietary approaches including High-protein, DASH, Low-sodium, Low-carbohydrate, Low-GI/GL and Paleolithic diets had no significant effect on DBP (Supplementary Fig. 4).

#### 3.6. Subgroup analysis

Subgroup analysis was performed based on duration of the intervention and sample size. Results of the subgroup analysis indicated that the dietary modifications had significant reducing effect on SBP in both less and more than 12 weeks and in studies with both less and more than 100 participants (Supplementary Fig. 5). However, we found that adopting healthful dietary modifications had significant effect on DBP in more than 12 weeks intervention and in studies with more than 100 participants (Supplementary Fig. 6).

## 4. Discussion

In this meta-analysis of 24 trials including 1130 T2D patients we compared the effects of 11 different dietary approaches (DASH, Low-fat, Low-carbohydrate, High-protein, Low-protein, Mediterranean, Paleolithic, Vegan, High-fiber Low-GI/GL, Low-sodium, and Korean-traditional).

**Table 1 – Characteristic of the included studies in meta-analysis.**

| Authors                    | Year | Country     | Study design   | Participants & Sample size (intervention/control) | Sex                     | Intervention                                       | Trial Duration (week) | Age (intervention/control) | Results (intervention group)                                 |
|----------------------------|------|-------------|----------------|---|-------------------------|--|-----------------------|----------------------------|--|
| P. M. Dodson, et al.       | 1984 | UK          | RCT            | T2D patients 25/25                                | M/F                     | High fiber, low fat, low sodium vs. regular diet   | 12 weeks              | 56.6 ± 7.2/ 56.9 ± 7.5 y   | Significant reduction in SBP & DBP                           |
| P.J.Pacy et al.            | 1986 | UK          | RCT            | T2D patients 35/18                                | M/F                     | High fiber, low fat, low sodium vs. regular diet   | 4 weeks               | 53.6 ± 8.5/ 55.3 ± 6.7 y   | Significant reduction in DBP & no significant change in SBP  |
| P M Dodson, et al.         | 1989 | UK          | RCT            | T2D patients 17/17                                | M/F                     | Moderate sodium restriction / Supine               | 12 weeks              | 61. 9 ± 7.5/ 61. 1 ± 6.3   | Significant reduction in SBP & no significant changes in DBP |
| P M Dodson, et al.         | 1989 | UK          | RCT            | T2D patients 17/17                                | M/F                     | Moderate sodium restriction / Erect                | 12 weeks              | 61. 9 ± 7.5/ 61. 1 ± 6.3   | Significant reduction in SBP & no significant changes in DBP |
| Toshiro Sugimoto, et al.   | 1991 | Japan       | RCT            | T2D patients 7/7                                  | M/F                     | low protein vs regular diet                        | 4 weeks               | 64.7 ± 4.4/ 49.3 ± 6.3 y   | No significant changes in SBP and DBP                        |
| Loek T. J. Pijls et al.    | 1999 | Netherlands | R/SB/CT        | T2D patients 58/63                                | M/F                     | low protein vs regular diet                        | 24 weeks              | 64 ± 8 / 63 ± 8 y          | Significant reduction in SBP & DBP                           |
| Loek T. J. Pijls et al.    | 1999 | Netherlands | R/SB/CT        | T2D patients 58/63                                | M/F                     | low protein vs regular diet                        | 52 weeks              | 64 ± 8/ 63 ± 8 y           | Significant reduction in SBP & DBP                           |
| Andrew S. Nicholson et al. | 1999 | USA         | RCT            | T2D patients 7/6                                  | M/F                     | low fat vegan diet vs low fat conventional diet    | 12 weeks              | 51/60 y                    | No significant changes in SBP and DBP                        |
| Frank Q. Nuttalla et al.   | 2006 | USA         | RCT cross-over | T2D patients 8/8                                  | M                       | high protein, low carbohydrate vs regular diet     | 5 weeks               | 61/61 y                    | No significant changes in SBP and DBP                        |
| Lopez, L. V, et al.        | 2008 | Mexico      | RCT            | T2D patients Normoalbuminuric 9/10                | M/F                     | low protein diet vs regular diet                   | 17.14 weeks           | 68.0 ± 9.3/ 66.3 ± 10.1    | No significant changes in SBP and DBP                        |
| Lopez, L. V, et al.        | 2008 | Mexico      | RCT            | T2D patients Microalbuminuric 10/12               | M/F                     | low protein diet vs regular diet                   | 17.14 weeks           | 68.0 ± 9.3/ 66.3 ± 10.1    | No significant changes in SBP and DBP                        |
| Lopez, L. V, et al.        | 2008 | Mexico      | RCT            | T2D patients Macroalbuminuric 10/9                | M/F                     | low protein diet vs regular diet                   | 17.14 weeks           | 68.0 ± 9.3/ 66.3 ± 10.1    | No significant changes in SBP and DBP                        |
| B. N. M. Yusof et al.      | 2009 | Malaysia    | RCT            | T2D patients 51/49                                | M/F                     | low-GI foods vs regular diet                       | 4 weeks               | NR                         | No significant changes in SBP and DBP                        |
| B. N. M. Yusof et al.      | 2009 | Malaysia    | RCT            | T2D patients 51/49                                | M/F                     | low-GI foods vs regular diet                       | 12 weeks              | NR                         | No significant changes in SBP and DBP                        |
| Tommy Jönsson, et al.      | 2009 | Sweden      | RCT/cross-over | T2D patients 13/13                                | M/F                     | Paleolithic diet vs. regular diet                  | 12 weeks              | 66 ± 6/ 63 ± 6             | Significant reduction in SBP & DBP                           |
| Hope R. Ferdowsian, et al. | 2010 | USA         | RCT            | T2D patients 68/45                                | M/F                     | low-fat, vegan diet                                | 22 week               | NR                         | No significant changes in SBP and DBP                        |
| Susan M Levin, et al.      | 2010 | USA         | RCT            | T2D patients 68/45                                | M/F                     | low-fat, vegan diet                                | 22 week               | 46 ± 10/ 42 ± 10           | No significant changes in SBP and DBP                        |
| Leila Azadbakht, et al.    | 2011 | Iran        | RCT            | T2D patients 31/31                                | M/F                     | DASH diet  | 8 weeks               | NR                         | Significant reduction in SBP & DBP                           |
| Tori Goldstein, et al.     | 2011 | Israel      | RCT            | T2D patients 26/26                                | M/F                     | low carbohydrate                                   | 6 weeks               | 57 ± 9/ 55 ± 8             | No significant changes in SBP and DBP                        |
| Tori Goldstein, et al.     | 2011 | Israel      | RCT            | T2D patients 22/22                                | M/F                     | low carbohydrate                                   | 12 weeks              | 57 ± 9/ 55 ± 8             | No significant changes in SBP and DBP                        |
| Tori Goldstein, et al.     | 2011 | Israel      | RCT            | T2D patients 20/20                                | M/F                     | low carbohydrate                                   | 24 weeks              | 57 ± 9/ 55 ± 8             | No significant changes in SBP and DBP                        |
| Tori Goldstein, et al.     | 2011 | Israel      | RCT            | T2D patients 14/16                                | M/F                     | low carbohydrate                                   | 52 weeks              | 57 ± 9/ 55 ± 8             | No significant changes in SBP and DBP                        |
| Asemi, Z. et al.           | 2013 | Iran        | RCT            | T2D patients 17/17                                | F                       | DASH diet  | 4 weeks               | 30.7 ± 6.7/ 29.4 ± 6.2     | Significant reduction in SBP & no significant changes in DBP |
| Luger, M. et al.           | 2013 | USA         | RCT            | T2D patients 22/22                                | M/F                     | High-Protein vs. standard diet                     | 4 weeks               | 61.0 ± 5.7/ 63.7 ± 5.2     | No significant changes in SBP and DBP                        |
| Luger, M. et al.           | 2013 | USA         | RCT            | T2D patients 22/22                                | M/F                     | High-Protein vs. standard diet                     | 12 weeks              | 61.0 ± 5.7/ 63.7 ± 5.2     | No significant changes in SBP and DBP                        |
| Mauro Giordano, et al.     | 2014 | Italy       | RCT            | T2D patients 40/34                                | M/F                     | Moderate Protein Diet vs regular diet              | 154.2 weeks           | 72/71                      | No significant changes in SBP and DBP                        |
| Su-jin Jung, et al.        | 2014 | Korea       | RCT            | T2D patients 21/20                                | M/F                     | Korean Traditional Diets vs regular diet           | 12 weeks              | 63.3 ± 2/ 60.2 ± 1.9       | No significant changes in SBP and DBP                        |
| Vasiliki Argiana, et al.   | 2015 | Greece      | RCT            | T2D patients 28/30                                | M/F                     | Low GI/GL hypocaloric vs. regular hypocaloric diet | 12 weeks              | 61.3 ± 1.4/ 63.0 ± 1.3     | Significant reduction in SBP & DBP                           |
| U Masharani et al.         | 2015 | USA         | RCT            | T2D patients 14/10                                | M/F                     | Paleolithic vs ADA diet                            | 2 weeks               | 58 ± 8/56 ± 13 y           | No significant changes in SBP and DBP                        |
| AE Bunner et al.           | 2015 | USA         | RCT            | T2D patients 17/17                                | M/F                     | high fiber diets vs usual diet                     | 20 weeks              | 57 ± 6/58 ± 6 y            | Significant reduction in SBP & DBP                           |
| Yu-Mi Lee, et al.          | 2016 | Korea       | RCT            | T2D patients 46/47                                | M/F                     | Vegan Diet vs. standard diabetic diet              | 4 weeks               | 57.5 ± 7.7/ 58.3 ± 7.0     | No significant changes in SBP and DBP                        |
| Yu-Mi Lee, et al.          | 2016 | Korea       | RCT            | T2D patients 46/47                                | M/F                     | Vegan Diet vs. standard diabetic diet              | 12 weeks              | 57.5 ± 7.7/ 58.3 ± 7.0     | No significant changes in SBP and DBP                        |
| Valeria Di Onofrio, et al. | 2018 | Italy       | RCT            | T2D patients 69/210                               | M/F                     | Mediterranean diet vs regular diet                 | 36 weeks              | 64 ± 5.57/ 65 ± 7.46       | Significant reduction in SBP & DBP                           |
| Reza Hashemi, et al.       | 2019 | Iran        | RCT            | T2D patients 40/40                                | F                       | DASH Diet vs ADA diet                              | 12 weeks              | 50/50                      | Significant reduction in SBP & no significant changes in DBP |
| Reza Hashemi, et al.       | 2019 | Iran        | RCT            | T2D patients 40/40                                | M                       | DASH Diet vs ADA diet                              | 12 weeks              | 50/50                      | Significant reduction in SBP & no significant changes in DBP |
| Reza Hashemi, et al.       | 2019 | Iran        | RCT            | T2D patients 40/40                                | M/F BMI < 30            | DASH Diet vs ADA diet                              | 12 weeks              | 50/50                      | Significant reduction in SBP & no significant changes in DBP |
| Reza Hashemi, et al.       | 2019 | Iran        | RCT            | T2D patients 40/40                                | M/F BMI greater than 30 | DASH Diet vs ADA diet                              | 12 weeks              | 50/50                      | Significant reduction in SBP & no significant changes in DBP |

RCT, randomized controlled trials; SB, single blinded; M, male; F, female; SBP, systolic blood pressure; DBP, diastolic blood pressure; T2D, type II diabetics; NR, Not reported.

**Table 2 – Quality Assessment (Method: Cochrane Collaboration’s Tool for Assessing Risk of Bias).**

| Article                         | Selection Bias                   |                           | Performance Bias<br>Blinding of<br>Participants<br>and Personnel | Detection Bias<br>Blinding of<br>Outcome<br>Assessment | Attrition Bias<br>Incomplete<br>Outcome Data | Reporting Bias<br>Selective<br>Reporting | Other Bias<br>Anything Else,<br>Ideally Pre-specified | Total<br>Low on Risk of Bias |
|---------------------------------|----------------------------------|---------------------------|--|--|--|--|---|------------------------------|
|                                 | Random<br>Sequence<br>Generation | Allocation<br>Concealment |  |  |  |  |   |                              |
| P. M. Dodson, et al. 1984       | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| P.J.Pacy et al. 1986            | Low                              | High                      | Unclear  | High   | High   | Low                                      | Low   | 3/7                          |
| P M Dodson, et al. 1989         | Low                              | High                      | High   | High   | High   | Low                                      | Low   | 3/7                          |
| Toshiro Sugimoto, et al. 1991   | High                             | High                      | Unclear  | Unclear  | High   | Low                                      | Low   | 2/7                          |
| Loek T. J. Pijls et al. 1999    | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| Andrew S. Nicholson et al. 1999 | Low                              | High                      | High   | High   | Low  | Low                                      | Low   | 4/7                          |
| Frank Q. Nuttalla et al. 2006   | Low                              | Low                       | High   | Unclear  | Low  | Low                                      | Low   | 5/7                          |
| Lopez, L. V, et al. 2008        | Low                              | High                      | High   | Low  | Low  | Low                                      | Low   | 5/7                          |
| B. N. M. Yusof et al. 2009      | Low                              | Unclear                   | High   | High   | Low  | Low                                      | Low   | 4/7                          |
| Tommy Jönsson, et al. 2009      | Low                              | Low                       | High   | Low  | Low  | Low                                      | Low   | 6/7                          |
| Hope R. Ferdowsian, et al. 2010 | High                             | High                      | High   | High   | Low  | Unclear                                  | Low   | 2/7                          |
| Susan M Levin, et al. 2010      | High                             | High                      | High   | High   | Low  | Low                                      | Low   | 3/7                          |
| Leila Azadbakht, et al. 2011    | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| Tori Goldstein, et al. 2011     | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| Asemi, Z. et al. 2013           | Low                              | High                      | Low  | Low  | Low  | Low                                      | Low   | 6/7                          |
| Luger, M. et al. 2013           | Low                              | Low                       | High   | Low  | Low  | Low                                      | Low   | 6/7                          |
| Mauro Giordano, et al. 2014     | High                             | High                      | High   | High   | Unclear                                      | Low                                      | Low   | 2/7                          |
| Su-Jin Jung, et al. 2014        | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| Vasiliki Argiana, et al. 2015   | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| U Masharani et al. 2015         | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| AE Bunner et al. 2015           | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |
| Yu-Mi Lee, et al. 2016          | Low                              | High                      | High   | High   | Low  | Low                                      | Low   | 4/7                          |
| Valeria Di Onofrio, et al. 2018 | High                             | High                      | High   | High   | Low  | Low                                      | Low   | 3/7                          |
| Reza Hashemi, et al. 2019       | Low                              | Low                       | High   | High   | Low  | Low                                      | Low   | 5/7                          |

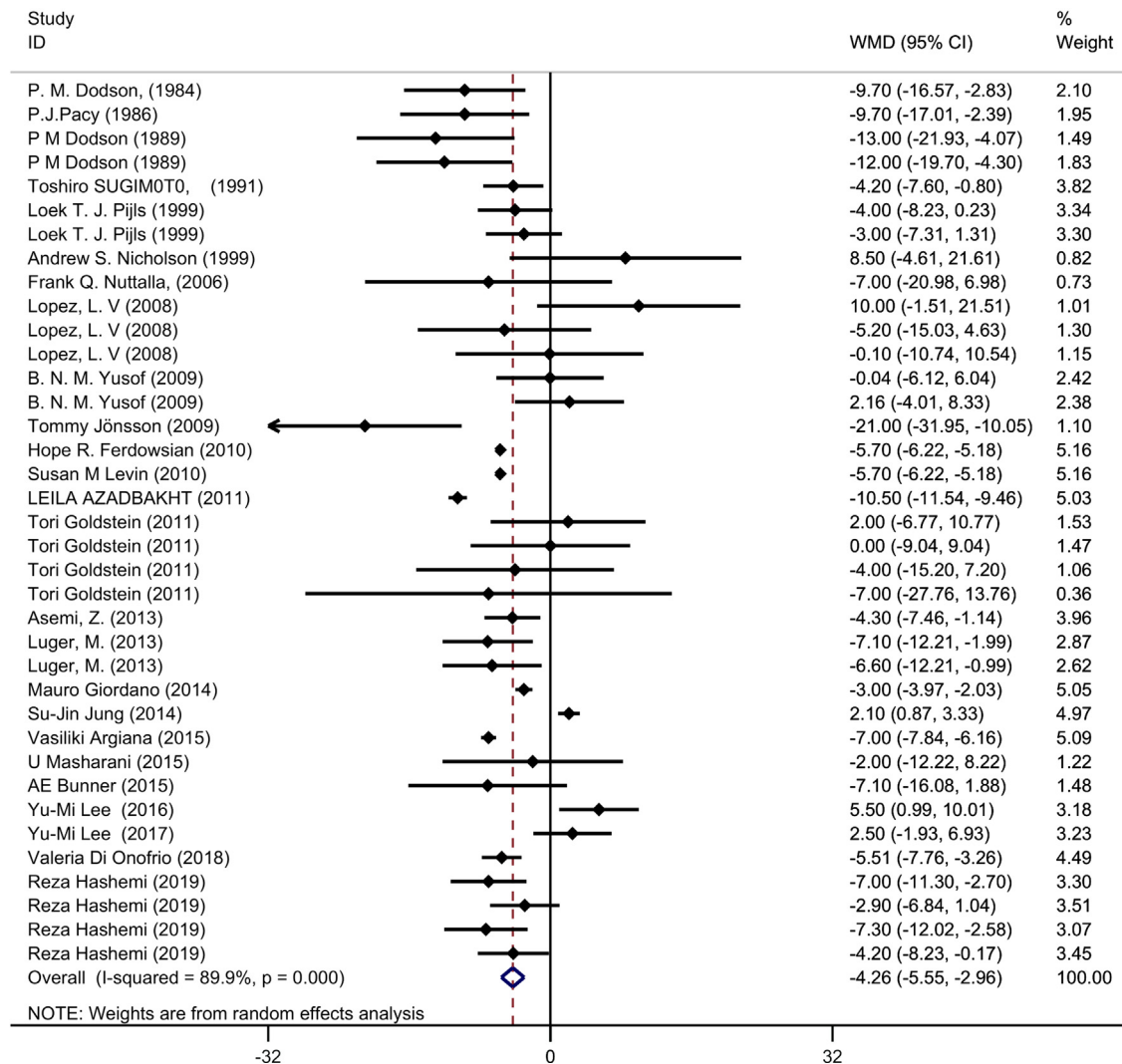


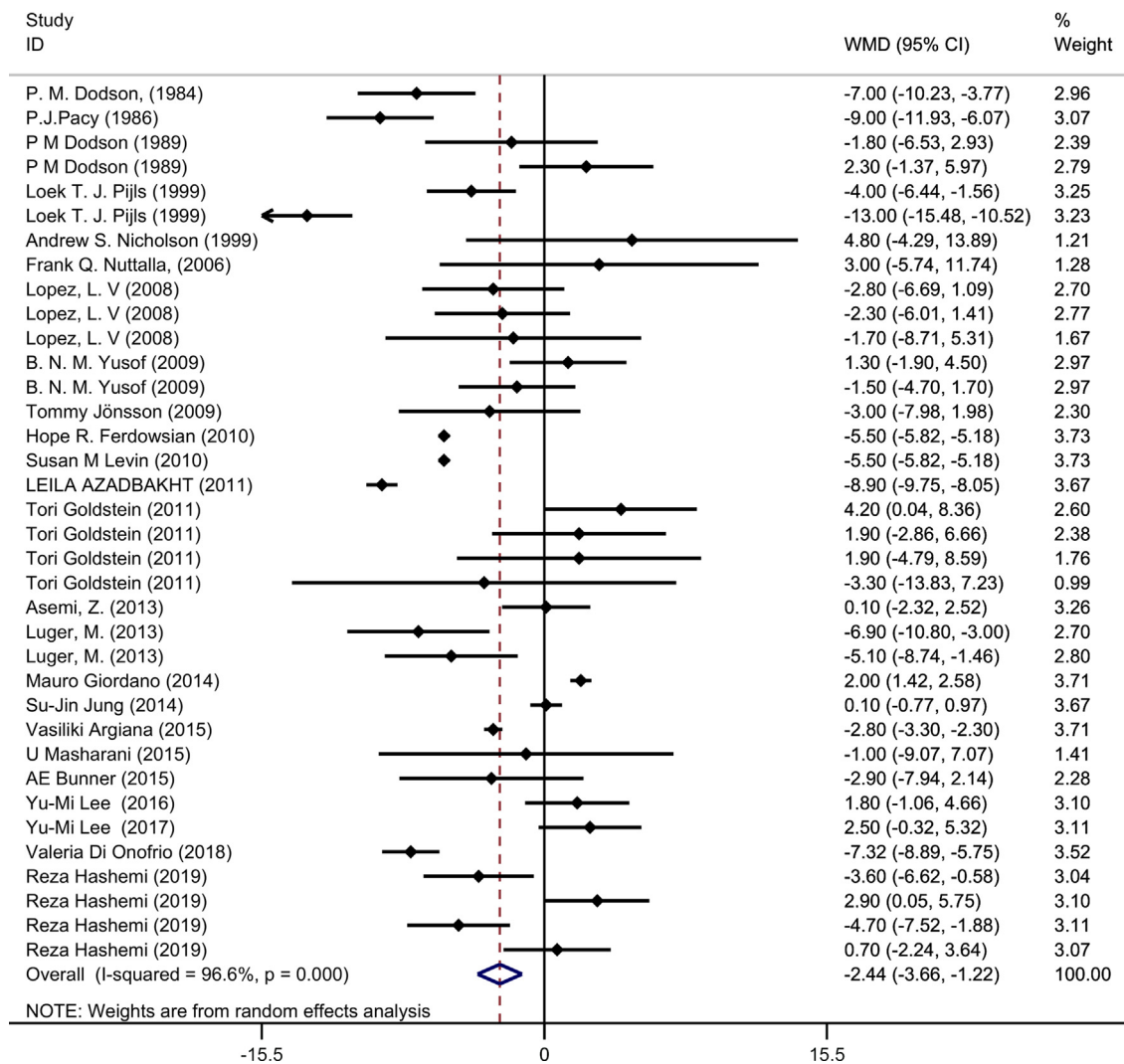
Fig. 2 – Forest plot of the effect of dietary modifications on systolic blood pressure.

Results of our meta-analysis demonstrated that adopting healthful dietary modifications were more effective in reducing both SBP and DBP vs. control. According to our meta-analysis Low-sodium diet was ranked the most effective dietary approach in reducing SBP, followed by the High-fiber, and the DASH diet. In terms of effect on DBP, High-fiber diet was ranked the most effective dietary approach in reducing DBP, followed by the Low-fat and Low protein diet. The Low-sodium, High-fiber, DASH, Low-fat, High-protein, Low-protein and Vegan dietary approach were significantly more effective in reducing SBP ( $-10.84$  to  $-3.05$  mmHg) compared to a control diet. On the other hand, the High-fiber, Low-fat, Low-protein and Vegan diet were significantly more effective in reducing DBP ( $-7.28$  to  $-3.1$  mmHg) in comparison with a control diet.

It has been shown that the prevalence of hypertension is increased in diabetes mellitus (DM) patients [40]. Hypertension is a major risk factor for cardiovascular disease, which has an important role in the morbidity and mortality of DM patients [40]. The importance of the reduction in BP is strengthened by the previous studies which have indicated that

an approximately 10 mmHg decline in SBP, reduced the risk of cardiovascular disease by 20%, heart failure by 28%, stroke by 27%, and all-cause mortality by 13% [41]. Furthermore, a decrease of approximately 5 mmHg in DBP was associated with a reduction in the risk of stroke by 32% and ischemic heart disease by 20% [42]. A meta-analysis demonstrated that even 2 mmHg decrease in SBP was associated with a decrease in risk of death due to stroke by 10%, and due to ischemic heart disease by 7% [43].

Although this is the first meta-analysis to assess the effects of different dietary approaches on BP in T2D patients, several previous meta-analyses have assessed only one dietary approach or mixing in normotensive and hypertensive subjects and found contradictory results. In 2016, a meta-analysis of 24 randomized trials including normotensive and hypertensive participants indicated that the DASH, a low-sodium and a low-calorie diet were more effective in reducing both SBP and DBP, whereas, the Mediterranean diet led to a decrease only in DBP compared to control [44]. Recently, another meta-analysis including hypertensive and pre-hypertensive patients reported that the DASH, Mediter-



**Fig. 3 – Forest plot of the effect of dietary modifications on diastolic blood pressure.**

ranean, low-carbohydrate, Paleolithic, high-protein, low-glycemic index, low-sodium, and low-fat dietary approaches were significantly more effective in reducing SBP and DBP in comparison to a control diet [10]. According to the results of these meta-analyses, among the different dietary approaches, the DASH diet was associated with the greatest overall reduction in both SBP and DBP. While according to our meta-analysis both the Low-sodium and High fiber diets had the greatest lowering effect on SBP ( $-10.84$  and  $-9.08$  mmHg, respectively), and the High-fiber diet had the greatest lowering effect on DBP ( $-7.28$  mmHg) in T2D patients. When considering both the systolic and diastolic blood pressures, it can be concluded that a High-fiber diet is more effective in T2D patients.

Previous reviews have reported a significant inverse relationship between fiber consumption and BP [45]. In 2015, a meta-analysis reported reductions in both SBP and DBP in the High-fiber group, but larger reductions were seen from participants with a higher beta-glucan intake [46]. It is possible that the reduction in BP following high fiber diet, might partly be due to weight loss [46,47]. One of the most important recommendations in the management of hypertension is the

maintenance of a healthy weight [48]. It has been shown that for every 1 kg weight loss, SBP and DBP would decrease by 1 mmHg [48]. Moreover, evidence suggested that soluble fibers reduce BP through its effects on peripheral sensitivity to insulin [49]. Numerous studies have reported that higher concentrations of fermentable fiber in the gut are accompanied by improvement of insulin sensitivity [50].

Results of our meta-analysis indicated that although, the Low-sodium diet had significant greater lowering effect on SBP compared with control group, it has no significant effect on DBP. Numerous studies have reported that the Low-sodium diet had no significant effect on DBP. A recent study demonstrated that a Low-sodium diet significantly reduced SBP, whereas, it had no significant effect on DBP [51]. In 2017, a Cochrane meta-analysis indicated that sodium restriction (below the recommended upper level) in white participants with normotension, reduced SBP, but not DBP [52]. It should be noted that in most of the studies included in our meta-analysis, participants were normotensive or prehypertensive. Therefore, result of our study regarding the effects of the Low-sodium diet on SBP and DBP is in line with previous finding.



In addition, we found that the Dash diet had significant lowering-effect on SBP, but not on DBP compared with control group. The beneficial effects of DASH diet on both SBP and DBP have been shown in numerous studies. According to the previous systematic reviews and meta-analyses DASH diet reduced both SBP and DBP regardless of duration of the interventions, with or without weight loss, study sample size, and in both pre-hypertensive or hypertensive participants [10,53]. However, it has been reported that DASH diet is more effective in reducing BP in hypertensive subjects than in normotensive or pre-hypertensive subjects, and it has the potential to prevent hypertension in pre-hypertensive subjects [54]. The reasons for this discrepancy between the results of our meta-analysis and other meta-analysis might partly, be due to the difference in subjects included, and other possible mechanisms not fully understood. Further studies in this area will reveal more facts.

As the results of our meta-analysis indicated, vegan diet was also more effective in reducing both SBP and DBP in T2D patients. Result of our study is in line with a meta-analysis by Yokoyama *et al.*, [55] which indicated that vegetarian diet reduced both SBP and DBP. In addition, we found that both the Low-carbohydrate and Low-GI/GL diets had no significant effect on BP in T2D patients. Previous meta-analyses indicated conflicting results regarding the effect of the Low-carbohydrate and Low-GI/GL diet on BP. In 2013, a meta-analysis reported that low-carbohydrate diet had no significant effect on SBP, but reduced DBP [56]. Another meta-analysis included healthy adults revealed that low-carbohydrate diet had no significant effect on both SBP and DBP [57]. Moreover, results of previous meta-analyses regarding the effect of High/Low-protein and Low-fat diets are also contradictory. A meta-analysis reported that the High-protein diet had no significant effect on both SBP and DBP [58]. However, a recent meta-analysis included pre-hypertensive and hypertensive participants indicated that both High-protein and Low-fat diets were significantly more effective in reducing both SBP and DBP [10]. Results of our meta-analysis indicated that both Low-protein and Low-fat diets were more effective in reducing SBP and DBP vs. control diet, whereas, High-protein diet were effective in reducing SBP, and not DBP. Contradictions found in the results of the meta-analyses regarding the effects of different dietary approaches on BP could partly be due to the difference in participants included in these meta-analyses. Most of the previous meta-analyses had no restriction on the similarity of studies based on the types of participants and included both healthy subjects and patients with different types of diseases. Therefore, more studies are needed in this area.

Present systematic review and meta-analysis has several strengths. First, this is the first meta-analysis to assess the comparative effects of different dietary approaches on BP in T2D patients. Second, we included RCTs which examined complementary endpoints, providing a comprehensive review on this topic. Third, this review is based on an up to date literature search from a large number of databases and included 24 studies with 1130 participants in the intervention arm and 1247 participants in the control arm. An important limitation of this meta-analysis is the low number of trials which were available for each dietary approaches that limits

the strength of the conclusion of the present meta-analysis separately for each of the dietary approaches; however, we hope this study will be helpful for future studies.

In conclusion, results of our systematic review and meta-analysis have important clinical and public health implications, suggesting that dietary modifications are an effective method for controlling BP among T2D patients. When considering both SBP and DBP, the High-fiber diet had the greatest effect on lowering BP in these patients, however, further well-designed studies are needed to confirm the results of the present meta-analysis.

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## Author contributions

AA and RC designed the study. PK and FF reviewed and selected the articles. PK and FF extracted needed data from articles. AA performed data analysis and interpretation. RC drafted the manuscript. EF and MJG revised the article for important intellectual content.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2020.108108>.

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