**Supplemental Figure 1**

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**Supplemental Table S1.** Summary of additional studies on DASH diet worthy of consideration

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| Study # | Citation | Study Type | Description | Subjects | Duration | Findings for DASH Diet | Comments (Does the study support claims of benefit from each eating pattern, overall?) |
| 1 | Blumenthal J, 201023 | RCT (ENCORE study) | Compared DASH; DASH + exercise + E- restriction; usual care  | n=144 adults140 (97%) completed studynadults with prediabetes or T2D= 50 Completion n unknown | 4 months | **In those with prediabetes and T2D:** **♦** % who improved in at least 1 category: DASH + exercise/E-restriction – 72%DASH alone – 54%UC – 42%**♦ In participants without diabetes or prediabetes at baseline - during the trial period diabetes classification worsened in:**2% of DASH + exercise16% in DASH alone11% in UC.  | **Limited support for claims.**  |
| 2 | Paula TP, 201524 | RCT | Compared DASH diet + exercise vs ADA-recommended diet + no exercise in adults with T2D and uncontrolled hypertension.  | **n=**40adults with T2D and high blood pressuren that completed study is unknown | 4 weeks | **♦ BP** DASH arm significantly improved.**♦ HbA1c** both diets improved SS WG; BG nSS.**♦ FBG** DASH only improved WG SS; BG nSS.**♦ TG, LDL** DASH only improved WG SS; BG nSS. **♦ Total C and HDL** nSS WG, nSS BG for both diets.**♦ BMI** WG nSS, BG nSS | **Limited support for claims.**  |

**Supplemental Table S2.** Summary of additional studies on Mediterranean diet worthy of consideration

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| Study # | Citation  | Study Type | Description | Subjects | Duration | Findings for Med Diet | Comments (Does the study support claims of benefit from each eating pattern, overall?) |
| 1 | Toobert D, 200332 | RCT | Med diet vs. control diet (usual care). No E-restriction. Included exercise and intensive behavioral support.Main outcomes included HbA1c, lipids, BMI, blood pressure. | n=279 postmenopausal women with T2Dn that completed the study is unknown | 6 months | **BG SS findings favored Med diet****♦ HbA1c** AR ↓0.36% (↓4.8%) BG SS**♦ BMI** AR ↓0.37kg/m2 (↓1.0%) BGSS**♦ Lipids, blood pressure** BG nSS | **Supports claims.** |
| 2 | Maiorino, 201733 | RCT follow up | Follow up to Esposito 2009 and Esposito 2014. Assessed the long-term effects of a Mediterranean diet, compared to a low-fat diet, on circulating levels of endothelial progenitor cells (EPCs) and the carotid intima-media thickness (CIMT) in patients with T2D | n=215 adults with newly diagnosed T2D101 (47.0%) completed study | End of trial varied with diet (based on mean years at which diabetes drugs needed)  | **Results at EOT (mean follow-up 5.2 years Med diet; 3.5 years low-fat diet):****♦ CIMT** Med diet AR↓0.026 mm (↓3.1%); low-fat diet AR ↓0.001 mm (↓.01%) BG SS**♦ Circulating EPCs** On 7 measures, 5 were BG SS, favoring Med diet **♦ HbA1c** Med diet AR ↓.7% (↓9.0%); low-fat AR .4% (5.0%) BG SS**♦ HDL** Med diet AI3mg/dL (↓7.0%); low-fat 0mg/dL (↓0%); BG SS**♦ HOMA** Med diet AR↓1.5 (↓28.8%); low-fat AR ↓.8 (↓15.1%); BG SS **♦ Weight** Med diet AR ↓3.7kg (↓4.3%); low-fat diet AR ↓2.9kg (↓3.4%) BG SS **♦ Total C, FBG** BG nSS**♦ Mean years at which diabetes drugs needed** Med diet, 5.2 years; low-fat diet, 3.5 years. | **Supports claims.** |
| 3 | Esposito, 201434 | RCT follow up | Follow up to Esposito 2009, which tested Med diet for efficacy in delay of medication initiation in patients newly diagnosed with T2D. | Original n **=** 215overweight persons newly diagnosed with T2D | End of trial varied with diet (based on mean years at which diabetes drugs needed) | **♦ Mean years at which diabetes drugs needed Med diet,** 4.8 years; low-fat diet, 2.8 years. **♦ % experiencing T2D remission (partial or complete) at yr 6:** Med diet, 5.0%; low-fat diet, 0%.**♦ % experiencing complete T2D remission at yr 4:** Med diet ,1.9%; low-fat diet 0%**♦** all Med diet participants required diabetes medications at 8.1 years.all low fat participants required medications at 6.1 years | **Partially supports claims.** |
| 4 | Ceriello, 201435 | RCT | Tested effects of a Med diet supplemented with olive oil vs a control low-fat diet  | n=24 adults with T2Dn completed unknown | 3 months | **♦ Flow-mediated dilatation (FMD)** Med diet AR ↓2.3% (↓29.1%) WG SS; low-fat, WG nSS.**♦ In addition to FMD Med diet** SS improved 4 other markers for inflammation and reduced negative effects of acute hyperglycemia induced by hyperglycemic clamp. WG SS; low-fat diet WG nSS on all.**♦ HbA1c, BMI, SBP, DBP, total C, TRG, HDL, LDL** WG nSS, BG nSS for both diets. | **Partially supports claims.** |
| 5 | Shai I, 200836 | RCT | Compared Med, low-carb, and low-fat diets. | n=322 moderately obese adults with T2D;included 46 adults with T2D 36 (78%) with T2D completed study | 2 years | **In those with T2D:****♦ FBG** better with Med diet; BG SS (vs low-fat diet)**♦ HOMA-IR** better with Med diet; BG SS (vs low-fat diet)**♦ HbA1c**Low-fat AR ↓0.4% WG nSSMed AR ↓0.5% WG nSSLow-carb AR ↓0.9% WG SSBG nSS | **Supports claims.** |
| 6 | Itispoulos, 201037 | RCT | Investigated the impact on metabolic control of a diet modeled on the traditional Cretan Med diet in T2D | n=3127 (87%) completed study | 12 weeks | **For Med diet:****♦ HbA1c AR** ↓.3% (4.2%) BG SS for Med diet**♦ BMI, FBG, fasting insulin, total C, HDL, LDL, TRG, SBP, DBP, CRP, HOMA** BG nSS | **Partially supports claims.**  |
| 7 | Esposito, 201038  | Systematic review and meta-analysis | assessed the effect of the Med diet management and prevention of T2D. | Included 5 RCTs on persons with T2D | varied | **♦ FBG (4 RCTs)** AR range 7-40mg/dL. BG SS,favoring Med diet.**♦ HbA1c** (4 RCTs) AR range0.1-0.6%. BG SS favoring Med diet. **♦ HOMA** (3 RCTs) favored Med diet.  | **Supports claim** |
| 8 | Esposito, 2015 39 | Systematic review and meta-analysis  | Summarized the evidence about the efficacy of the Med diet on the management of T2D and prediabetic states.  | 8 meta-analyses and 5 RCTs included.  |  | **♦ HbA1c from meta-analysis of 3 trials on T2D (≥ 6 mos, pooled n=673)** favored Med diet, WMD= -.47% BG SS**♦ HbA1c from meta-analysis of 4 meta-analyses on T2D.** Favored Med diet, AR range ↓0.30-.47%. | **Supports claims.** |
| 9 | Ajala O, 201340 | Systematic review and meta-analysis  | Assessed the effect of diet types on glycemic control, lipids, and weight loss. Based on search to Aug 2011 for RCTs of ≥ 6 mo. Includes 4 studies on Med diet. | Adults with T2D |  | Found the Med diet superior to other diets for glycemic control (HbA1c) and weight loss; improved TRG, HDL, need for diabetes medication.  | **Supports claims.** |
| 10 | Huo R, 201541 | Systematic review and meta-analysis  | Meta-analysis of RCTs to explore the effects of the Med diet, compared to control diets, on glycemic control, weight loss and CVD risk factors in persons with T2D. Included 9 studies. Based on search of literature to Feb 2014. | Adults with T2D |  | Med diet resulted in greater improvement in HbA1c, FBG, fasting insulin, blood pressure, weight loss, HDL and TRG than control diets.  | **Supports claims.** |
| 11  | Pan B, 201842 | Systematic review/ network meta-analysis | Compared the differences between major dietary patterns (Mediterranean, low-carb, low-fat) in improving glycemic control,cardiovascular risk, and weight loss for patients with T2D | 10 RCTs (2006 to 2016) |  | **♦** Included studies were on Mediterranean, low-fat, low-carb, high-carb, and regular diets. **♦** The only BG SS mean differences: 1) high-carb superior to regular diet for HDL (1.04mmol/L MD); 2) Med diet superior to low-fat for HbA1c (-.45% MD); FBG (-1.24mmol/L MD); weight (-1.18kg MD); waist size (-0.73 cm MD); HDL (0.07mmol/L MD); total C (-0.17mmol/L MD); and TRG (-0.21mmol/L MD).**♦** No other between-diet comparisons found SS differences between diet types. **♦** The Med diet was ranked as having the highest probability of being the best diet for improving glycemic control (HbA1c), weight, waist circumference, CVD risk (LDL, total C, TRG**).**  | **Supports claims.** |
| 12 | Schwingshackl L, 201843 | Systemic review and network meta-analysis | Compared the efficacy of different dietary approaches on glycemic control in T2D. Nine dietary approaches were included low-fat, vegetarian, Mediterranean, high-protein, moderate-carbohydrate, low-carbohydrate, control, low GI/GL, Paleothilic). Lit search through July 2017. 56 trials were included, published between 1978 and 2016.  | Adults with T2D | > 12 weeks | **For Med diet:****♦ HbA1c** AR↓0.79% vs control**♦ Fasting glucose** AR↓1.61mmol/L vs control | **Supports claim** |

**Supplemental Table S3.** Summary of additional studies on plant-based diets worthy of consideration

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Study # | Citation | Study Type | Intervention | Subjects | Duration | Findings | Comments (Does the study support claims of benefit from each eating pattern, overall?) |
| 1 | Barnard N, 201855 | RCT | Tested efficacy of low-fat vegan diet vs. control diet in clinical setting. E-restricted only in control diet. | **n=**45 obese adults with T2D40 (89%) completed study | 20 weeks | **For plant based:** **♦ HbA1c** AR ↓0.4%(**↓**6.0%) WG SS, BG nSS**♦ Weight** AR↓6.3kg(**↓**6.4%) WG SS, BG nSS♦ **SBP, DBP** nSS♦ **LDL** AR ↓11.9mg/dL (↓15.7%) WG SS, BG nSS♦ **HDL** AR ↓3.4mg/dL (↓6.2%) WG SS, BG nSS♦ **TRG** AR ↑20.8mg/dL (13.3%) WG nSS, BG nSS. | **Limited support for claims.** |
| 2 | Kahleova H, 201456 | RCT follow up | Follow up from Barnard 2006. Compared E-restricted vegetarian and conventional diabetic diets on body fat, IS, oxidative stress.  | n=62 obese adults with T2D in original study n at FU=44 (71%)  | 1 year after end of 6-month RCT | **For plant based:****♦ HbA1c** AI ↑0.49% WG SS, BG nSS**♦ Diabetes medication use hypoglycemics AI** ↑14%; insulin introduced AI ↑5% **♦ Weight** ARnSS at 1 yr (at 6 mo, AI ↑1.7kg, WG SS)♦ **Lipids** nSS (WG SS improvement at 6 mo)**♦** Most of the positive results at end of original study and at 6-mo FU were not sustained at 1-yr FU. | **Limited support for claims.**  |
| 3 | Lee Y, 201657 | RCT | Compared vegan diet to Korean Diabetes Assn. diet.  | n=106adults with T2D93 (88%) completed study | 12 weeks | **For vegan diet:** **♦ HbA1c AR** ↓0.5% (↓6.5%) WG SS, BG SS favored vegan diet**♦ Weight** AR BMI ↓0.5kg/m2 (↓2.1%) WG SS, BG nSS**♦ Lipids, blood pressure** nSS | **Supports claims.** |
| 4 | Mishra S, 201358 | Multi-site trial with sites randomized for test and control arms | Worksite program comparing no diet change to low-fat vegan diet for weight, lipids, blood pressure and HbA1c. | **n=**291 subanalysis of T2Dn=43 35 (81%) with T2D completed study | 18 weeks | **For plant-based with T2D:****♦ HbA1c** AR↓0.6% (↓9.8%)WGSS, BG SS **♦ Lipids not reported separately for T2D but for overall completers in plant based arm:** **♦ TRG: AR** ↑13.9 (10%) WG SS**♦ HDL: AR** ↓3.3 (9%) WG SS**♦ LDL: AR** ↓13 (12%) WG SS**♦Weight: AR** ↓4.3 (6%) | **Partially supports claims** |
| 5 | Ferdowsian H, 201059 | Non-randomized, two-site trial | To determine whether a multicomponent intervention program at a corporate site in is effective in reducing body weight and improving cardiovascular risk factors in overweight individuals. | n=113 adultswith a BMI of kg/m2 and/or previous diagnosis **o**f T2D.n with T2**D=**19; 100% completed | 22 weeks | **For plant-based with T2D:****♦ HbA1c** AR↓0.3%(↓4.1%) WG nSS, BG nSS**♦** Among those without medication changes (data not reported), **HbA1c** AR↓0.9% (n=5) in the intervention vs AR ↓0.2% (n=6) in the control. SS not reported. | **Limited support for claims.**  |
| 6 | Berman MA, 201860 | Single arm demonstration  | Tested PB diet + exercise intervention that used digital therapeutics for glycemic control and medication use. HbA1c results were patient-reported. | n=118 adults with T2D96 (81%) completed | 12 weeks | **♦ HbA1c** AR↓ 0.8% (↓9.9%) SS | **Supports claims.** |
| 7 | Schwingshackl L, 201843 | Systemic review and network meta-analysis | Compared the efficacy of different dietary approaches on glycemic control in T2D. Nine dietary approaches were included low-fat, vegetarian, Mediterranean, high-protein, moderate-carbohydrate, low-carbohydrate, control, low GI/GL, Paleothilic). Lit search through July 2017. 56 trials were included, published between 1978 and 2016.  | Adults with T2D | > 12 weeks | **♦ HbA1c** AR↓0.67% vs control**♦ Fasting glucose** AR↓1.29mmol/L vs control | **Supports claims.** |
| 8 | Yokoyama Y, 201461 | Systematic review and meta-analysis | Lit search 1900 through Dec 9 2013 for trials on PB diet in adults with T2D ≥ 4 weeks and reporting HbA1c and FBG. Six studies included: 4 RCTs and two clinical trials. A follow-up study was excluded which may have impacted findings | Adults with T2D | 4-22 weeks | **HbA1c** Mean absolute difference between test and control diets was 0.39%. favored vegan diet | **Supports claims.**  |
| 9 | Ajala O, 201340 | Systematic review and meta-analysis | Lit search to August 2011 of RCTs ≥ 6 mo comparing various diet types. Included 2 RCTs on PB diets (Barnard, 2009 and Kahleova, 2011); these two studies were not included in the meta-analysis. |  |  | "...there is a suggestion that vegan and vegetarian diets might be beneﬁcial in improving glycemic control and inducing weight loss. However, there is a need for more studies to support the wider use of these diets in people with diabetes." | **Limited support for claims.** |

**Supplemental Table S4.** Summary of additional studies on the low-carbohydrate diet worthy of consideration

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Study # | Citation | StudyType | Description | Subject s | Duration | Findings for the Low-Carb Diet | Comments |
| Randomized Controlled Trials |
| 1 | Saslow L, 201785 | RCT | Compared ad libitum low-carb, ketogenic diet vs. moderate-carb, lower-fat, E-restricted diet | n=34 adults with T2D29 (85%) completed study. | 1 year | **The BG SS findings favored low-carb.****♦ HbA1c** AR↓0.5%(↓7.6%) BG SS **♦ Weight** AR↓7.9kg(↓7.9%) BG SS**♦ Fasting insulin** BG nSS**♦ HOMA2-IR** BG nSS**♦ HDL, TRG, LDL** BG nSS♦ **SBP, DBP** BG nSS**♦ TRG:HDL ratio** AR↓0.5 (↓22.7%) BG SS**♦ Diabetes medication use** Sulfonylureas or dipeptidyl peptidase-4 inhibitors: all 6 in low-carb diet group discontinued the meds by 12 months. BG SS**♦** Metformin: BG nSS | **Supports claims.** |
| 2 | Yamada Y, 2014 86 | RCT | Examined the effects of a non-E-restricted, low-carb diet vs. an E-restricted diet. | n**=**24 adults with T2D 24 (100%) completed study. | 6 months | **The BG SS finding favored low-carb.****♦ HbA1c** AR↓0.6%(**↓**8.6**%**)BG SS**♦ FBG** AR BG nSS**♦ Weight** WG nSS, BG nSS**♦ LDL, HDL, SBP, DBP** WG nSS, BG nSS **♦ TRG** AR↓58.2mg/dL(**↓**41.1%)WG SS BG nSS**Safety and Adverse Effects**"...no changes in the markers of the renal function (i.e., urinary nitrogen, Cr, eGFR and albumin-to-creatinine ratio) … in either group. A marker of the liver function, the alanine aminotransferase level, tended to improve in the low-carbohydrate group ..."  | **Partially supports claims.** |
| 3 | Guldbrand H, 2012 87 | RCT  | Compared the effects on HbA1c and weight loss of a low-fat diet vs. a low-carb diet.  | n=61 adults with T2D. 7 did not take part, but their outcomes data were included; 100% included in analysis. | 2 years | **♦ HbA1c** 6 mo AR↓0.4% (↓5.3%) 24 mo ↓0% Low carb diet WG SS at 6 mos. Low-fat diet WG nSS at all points.BG nSS at 24 mos.**♦ Weight** low carb WG SSAR at all points;↓2.0kg(**↓**2.2%)at 24 mo. Low-fat diet WG SS AR at all points. BG nSS at 24 mo.**♦ SBP and DBP** Both diet groupsWG SS AR at all points., BG nSS at 24 mo.**♦ HDL** WG SS AI at all points; ↑0.23mmol/L(↑20.4%) at 24 mo. BG SS. Low-fat diet WG SS worse at 12, 24 mo. **♦ LDL AR** ↓0.3mmol/l WG nSS**♦ Diabetes medication use** Insulin doses **↓** BG SS | **Limited support for claims.**. |
| 4 | Westman E, 2008 88 | RCT | Compared a very low-carb, ketogenic diet vs. an E-restricted low-glycemic index diet. | n=84 obese adults with T2D 49 (58%) completed study. | 24 weeks | **For low carbohydrate:****♦ HbA1c** AR↓1.5%(↓17.0%) WG SS, BG nSS**♦ FBG** AR↓19.9mg/dl (**↓**11.2%) WG SS BG nSS**♦ Weight** AR↓11.1kg(↓10.2%) BG SS**♦ Fasting insulin** AR↓2.2uU/mL (↓29.4%) WG SS; BG nSS**♦ HDL** AI**↑** 5.6mg/dL(**↑**12.7%)WG SS, BG nSS♦ **TRG** AR ↓67.5mg/dl (↓32.1%) WG SS, BG nSS♦ **Total C**, **LDL** WG nSS, BG nSS♦ **VLDL** AR ↓10.0mg/dl WG SS, BG nSS♦ **TRG:HDL ratio** AR **↓**1.8 (↓34.6%) WG SS, BG nSS**♦ Diabetes medication use**95.2% subjects reduced or eliminated meds. BG SS favoring low-carb.**♦ Adverse events:** symptomatic; most common - headache, constipation, diarrhea, insomnia, and back pain BG nSS for all. | **Supports claims.** |
| 5 | Samaha F, 2003 89 | RCT | To study the effects of a low-carb diet vs. a E-restricted, low-fat diet in severely obese individuals. inst to consume <30gr total of carbohydrates per day in low carbohydrate arm. | n=132 severely obese subjects most having dT2D or MetSyn; 79 (59.9%) completed the study. T2D sub-analysis conducted for FBG only. | 6 months | **Results low carbohydrate in participants with T2D:** **♦ FBG** AR↓26.0 mg/dL(↓15.5%) BG SS favoring low-carb.**♦ insulin level** AR↓8 (20%) BG nSS**♦ HbA1c** AR ↓0.6 (8%) BG nSS | **Supports claims.** |
| 6 | Tay J 2018 90 | RCT follow-up | Follow up to Tay 2014. Compared a very low-carb, high-unsaturated/low- saturated fat diet vs. a high-unrefined carb, low-fat diet on glycemic control and CVD risk in T2D.Both groups were E- restricted. | **n=**115 obese adults with T2D 61 (53%) completed study. | 2 years | **The BG SS findings favored low-carb.****♦ HbA1c** ↓0.7% in both groups BG nSS**♦ Glucose variability**Improved more in LC group BG SS**♦ Weight** maintained almost 7% weight loss in both groups for 2 years BG nSS**♦ TRG** AR↓.1mmol/L (↓6.3%) BG SS**♦ HDL** AI ↑0.02mmol/L (↑1.7%) BG SS**♦ LDL** WG nSS, BG SS favoring control diet.**♦ SBP, DBP, FBG, fasting insulin, HOMA2-IR, CRP, eGFR** BG nSS**♦ Diabetes medication use**Reduced more in low-carb arm BG SS | **Partially supports claims** |
| 7 | Wang L, 2018 91 | RCT | Compared a low-fat diet (recommended in China for T2D) to a low-carb diet for efficacy in control of blood glucose levels in persons with T2D | n=56 adults with T2D49 (88%) completed study. | 3 months | **♦ HbA1c** AR ↓.63% (↓8.5%) WG SS. Low-fat diet also WG SS. BG SS favoring low-carb.**♦ FBG** AR ↓1.41mmol/L (↓17.0%) WG SS. Low-fat diet also WG SS. BG nSS.**♦ BMI** AR ↓.77kg/m2 (↓3.2%) WG SS. Low-fat diet WG nSS. BG nSS.**♦ Total C** AR ↓.36mmol/L (↓7.4%) WG SS. Low-fat diet WG nSS. BG nSS. Other lipids not reported.**♦ Diabetes medication use** Both diets↓~3 insulin units/day. WG SS for both. BG nSS.**♦ Adherence** same degree of adherence in both groups | **Supports claims.** |
| 8 | Larsen RN, 201192 | RCT | To compare high protein, low carbohydrate (30% energy from protein and 40% energy from carbohydrate) with low protein, high carbohydrate diet (15% energy from protein and 55% energy from carbohydrate) | n= 99 obese or overweight adults with T2D 93 (94%) completed the study | 12 months | **All results for 40% carbohydrate arm****♦ HbA1c** 3 mo AR ↓0.52% (↓6.6%) 12mo AR ↓0.23% (↓2.9%) Time effect SS**♦ Weight** 3 mo AR ↓2.79kg (↓2.9%) 12mo AR ↓2.23kg (↓2.4%) Time effect SS**♦ HDL** 12 moAI **↑**0.08mmol/L (**↑**6.7%) Time effect SS**♦TRG** 12 mo AR ↓0.47mmol/L (↓19.7%) Time effect SS **♦ LDL** nSS | **Does not support** **claims** |
| 9 | Sato J, 201793 | RCT | To compared low carbohydrate diet (130gr) with calorie restricted diet in poorly controlled T2D in Japan | n=66 adults with T2D, 49 (94%) completed 6-month follow-up | 6 months | **BG results favored low-carb.****♦ HbA1c** AR↓0.65% WG SS, BG SS**♦ Weight** AR↓1.6kg WG SS, BG SS**♦ TRG, LDL, HDL** BG nSS | **Support claims** |
| Crossover trials |
| 10 | Boden G, 200594  | Crossover trial | Metabolic ward study.Compared effects first 1-week of a usual care diet (hospital food + food from "outside") followed by strict low-carb diet for 2 weeks. | n=10 obese adults with T2D10 (100%) completed study. | 7 days on usual care diet; 14 days on low-carb diet | **Results after 2 weeks carbohydrate restriction:****♦ HbA1c** AR↓0.5%(↓6.8%) SS**♦ FBG** AR↓22.0mg/dL(**↓**16.3%) SS**♦ Weight loss after subtraction of water weight loss** AR↓1.65kg (↓2.4%) SS**♦ Insulin sensitivity** Serum insulin ↓ SS**♦ Rate of insulin-stimulated glucose disappearance** ↑200% SS**♦ TRG** AR↓57.5mg/dL (↓35.3%) SS**♦ LDL, HDL** nSS**♦ Total C** AR↓17mg/dL(**↓**9.4%) SS | **Supports claims.** |
| 11 | Gannon MC, 200495 | Crossover RCT | Investigated the effect on glycemic control of a non-ketogenic low-carb, high-protein diet in adults with T2D. The test diet was the formulated low-biologically-available-glucose (LoBAG) diet. Weight loss was not a goal of this study. Control diet was based on recommendations of the American Heart Association. | n=8 overweight men with T2D 8 (100%) completed study. | 5 weeks on each diet with a 5-week washout between the two diets | **For the low carb diet:****♦ FBG** AR↓48mg/dL(↓28.7%) SS**♦ Fasting insulin** nSS**♦ Mean 24-h integrated net glucose area response** ↓77% SS**♦ Total 24-h integrated glucose area** **response** ↓36.3% SS **♦ TRG** AR **↓**20mg/dL(↓8.8%)SS**♦ Total C, HDL, LDL** nSS | **Supports claims.** |
| Non-randomized trials |
| 12 | Haimoto H, 2008 96 | RCT | Compared low-carb diet vs. conventional diet. Results at 1 and 2 years. | n=133 adults with T2D 102 (77%) completed study. | 2 years | **BG SS findings favored low-carb.****♦ HbA1c** AR ↓0.7% (**↓**9.5%)BG SS**♦ BMI** AR↓1.3kg/m2(**↓**5.2%)BG SS**♦ LDL** AR↓5mg/dL(**↓**4.1%)BG SS**♦ Total C** AR↓5mg/dL(**↓**2.4%)BG SS**♦ Diabetes medication use**# patients on sulfonylureas reduced 43%, 57%, 94% for 3 drug types. . | **Partially supports claims.** |
| 13 | Sanada M, 201897 | Single arm retrospective  | Sought to determine if a moderately low-carb intervention is safe and efficacious as determined by safety data and HbA1c, lipids, blood pressure, liver and renal function and weight over 36 months in a Japanese population. | n=200 adults with T2D157 (79%) completed 36-month follow-up. | 36 months | **♦ HbA1c** AR↓.5% (↓6.3%) SS**♦ Total C** AR ↓6.7mg/dL (↓3.3%) SS**♦ LDL** AR↓8.9mg/dL (↓7.7%) SS**♦ TRG** nSS**♦ DBP AR** SS; **SBP** nSS**♦ Overall insulin and SU decreased and metformin and DPP-4 increased over 36 months****♦ Fasting glucose, HDL, TRG, weight** nSS | **Supports claims.** |
| 14 | Hallberg S, 2018 98 | Non-random- ized, controlled parallel-arm trial | Outcomes (see McKenzie 2017) for ongoing trial assessing the effectiveness and safety of a remote, continuous care intervention combined with a very low-carb ketogenic diet for T2D management. Compared to usual care. | n=349 overweight and obese adults with T2D 218 (83%) in test diet group completed. | 1 year | **The BG SS findings favored low-carb.****♦ HbA1c** AR **↓**1.3%(**↓**17.1%)BG SS**♦ FBG** AR **↓**1.95mmol/L (**↓**21.9%)BG SS**♦ Weight** AR **↓**13.8kg(↓11.8%) BG SS**♦** **HOMA-IR** AR **↓**6.82(**↓**55%)BG SS**♦ TRG** AR **↓**0.54mmol/L(**↓**24.2%)BG SS**♦** **HDL** AI **↑**0.20mmol/L(**↑**18.3%)BGSS**♦ LDL** AI **↑**0.26mmol/L (**↑**.3%)BGSS♦ **Total C:HDL ratio** AR ↓0.53 (10.8%) BG SS**♦ SBP** AR **↓**6.36mmHg(**↓**4.8%)BG SS**♦ DBP** AR **↓**3.51mmHg(**↓**4.3%)BG SS**♦ Diabetes medication use**Insulin therapy was reduced or eliminated in 94% of users; sulfonylureas were entirely eliminated.**♦ No adverse events** attributed to intervention. | **Supports claims.** |
| 15 | Krebs J, 2013 99 | Single-arm trial | Tested intervention based on the Atkins diet; with 3 phases and gradual increase of carb intake over time. | **n=**14 obese adults with T2D 12 (86%) completed study. | 24 weeks | **♦ HbA1c** At week 24 AR↓1.1%(**↓**14.9%) SS**♦ FBG** At week 12 AR↓2.1mmol/L(**↓**21.6%) SS; at week 24 AR↓1.7mmol/L (↓17.5%) nSS**♦ Weight** At week 24 AR↓9.7kg(↓8.1%) SS**♦ HOMA** At week 12SS improved;at week 24nSS**♦ HDL** At week24AI **↑**0.14mmol/L (**↑**17.5%)SS **♦ LDL** AI **↑**0.40mmol/L (**↑**12.1%)SS**♦ TRG** AR↓0.37mmol/L(↓25.0%) nSS **♦ SBP, DBP** nSS | **Supports claims.** |
| 16 | Hussain T, 2012 100 | Non-random- ized, 2-arm trial | Compared very low carb, ketogenic diet vs. E-restricted diet. Participants allowed to select diet.  | n=363 overweight and obese adults; 102 had T2D102 of those with T2D (100%) completed study. | 24 weeks | **For low carbohydrate:****♦ HbA1c** AR ↓1.2%(**↓**~19.2%) BG SS**♦ Weight** AR ↓12.5kg (**↓**12.0%)BG SS **♦ HDL, total C, TRG, LDL** SS improved**♦ Adverse effects**. Urea levels increased SS. The uric acid and creatinine levels decreased.  | **Supports claims.** |
| 17 | Sasakabe T, 2011 101 | Single-arm trial  | Investigated impacts on CVD risk and abdominal fat of a moderately low-carb diet in adults with T2D.Two arms were given different instructions based on participants' HbA1c levels. Those below <9.0% were asked to eliminatecarb-rich foods from their dinner; patients with an HbA1c level ≥ 9.0% were asked to eliminate carbs from breakfast and dinner.  | n=63 overweight and obese adults with T2D52 (83%) completed study. | 6 months | **♦ HbA1cMen** AR ↓1.9%(**↓**22.6%) SS**Women** AR ↓1.6%(**↓**18.6%)SS**♦ FBG** **Men** AR ↓21mg/dL(**↓**13.4%)SS**Women** AR↓20mg/dL(**↓**12.2%)nSS**♦ Weight****Men AR** ↓2kg (↓2.8%) SS**Women AR** ↓1.7kg (↓3.0%) SS**♦ Fasting insulin** nSS**♦ TRG** nSS**♦ LDL**Men nSSWomen AR ↓24mg/dL (↓15.3%) SS**♦ DBP, SBP** nSS♦ Visceral and subcutaneous adipose tissue, waist size SS ↓ men and women  | **Supports claims.** |
| 18 | Nielsen J, 2008 102  | Follow-up to a non-randomized2-arm trial  | Follow up to non-randomized controlled trial Nielsen 2005. Compared the effects on glycemic control and weight of a low-carb diet vs. a high-carb diet at 3, 6, 22, and 44 months.  | n in analysis at 44 mo.=23 obese adults with T2D | Original trial was 6 months; follow-up at 44 months | **For low carbohydrate:****♦ HbA1c** AR↓1.2%(**↓**15.0%)SS**♦ Weight loss** AR ↓7.5kg (↓7.5%) SS**♦ HDL AI ↑**0.2mmol/L(**↑**18.2%) SS **♦ Total C, TRG, TG:HDL ratio** nSS; **LDL** not reported.**♦ HDL:total C ratio** AI **↑.**2(**↑**18.2%) SS**♦ Diabetes medication use**Mean insulin use increase from18u at 6 months to 41u at 44 months. Start of study mean was 60u. | **Supports claims.** |
| 19 | Nielsen J, 2005 103 | non-randomizedcontrolled trial | Compared a low- carbohydrate to a low-fat diet both calorie restricted on fasting glucose, HbA1c, weight and BMI. 6 month intervention for both groups and then 1 year follow up. Full data not available. | Total N =31 with diabetes16 - low carbohydrate15 calorie restricted low fat | 6 monthstrial with 1-year follow up in low carbarm only | **6 months for low carbohydrate:****♦ HbA1c** AR ↓1.4% (↓18%)**♦ Lipids** not reported**♦ Diabetes medication use**Insulin reduction but not elimination in 8 of 11 insulin treated patients with average dose 60u reduced to18u.Insulin eliminated in 3 patients.SFU eliminated in 3 and reduced in 2**1 year:****♦ HbA1c** AR ↓1.0% (↓13%) | **Supports claims** |
| 20 | Dashti H, 2007104 | non-random- ized trial | Compared effects of low-carb, ketogenic diet on obese adults with normal blood glucose and obese adults with T2D. | Total n=64; 31 had T2D 100% completed. T2D sub-analysis conducted. | 56 weeks | **♦ FBG** AR↓5.6mmol/l (↓53.5%) SS**♦ Weight** AR↓24.5kg(↓22.7%) SS**♦ HDL** AI **↑**0.55mmol/L (**↑**53.5%)SS **♦ LDL** AR ↓1.78mmol/L(**↓**34.5%) SS**♦ TRG** AR ↓3.68mmol/L(**↓**78.5%)SS**♦ Adverse effects.** Urea decreased SS. "No significant alteration was noticed in renal function test." | **Supports claims.** |
| 21 | Yancy W, 2005105 | single-arm trial  | Tested the effectiveness of a low-carb, ketogenic diet for improving glycemic control in individuals with T2D | n=28 overweight and obese adults with T2D 21 (75%) completed the study. | 16 weeks | **♦ HbA1c** AR ↓1.2%(**↓**16.0%) SS**♦ FBG** AR ↓1.5mmol/L (↓16.6%) SS**♦ Weight** AR ↓8.7kg (↓6.6%) SS**♦ HDL** AI **↑**0.07mmol/L(**↑**7.6%)SS**♦ TRG** AR **↓**1.12mmol/L(**↓**41.6%)SS♦ **Total C**, **LDL** nSS♦ **SBP, DBP** nSS♦ **Diabetes medication use** Reduced or discontinued for 81% of subjects.♦ **Renal function** Urea, creatinine nSS♦ **Adverse events.** None related to the diet.  | **Supports claims.** |
| 22 | Dashti H, 2004106 | single-arm trial | To determine effects of ketogenic diet on glucose, weight, and lipids | n=83 obese adults with high FBG (>7 mmol/L or 125mg/dL). Sample mean=7.26mmol/L; 131mg/dL.n completing study unknown | 24 weeks | ♦ **FBG** AR**↓** 1.6mmol/L(**↓**22.6%) SS♦ **Weight** AR**↓** 14.4kg(↓14.2%) SS♦ **HDL** ↑ SS♦ **Total C**, **LDL** ↓ SS♦ **TRG** AR ↓1.7mmol/L (↓60.4%) SS♦ **Renal function** urea and creatinine nSS | **Supports claims.** |
| Systematic Reviews and Systematic Review/Meta-analyses |
| 23 | Huntriss R, 2017107 | Systematic review and meta-analysis | Evaluated the effects on HbA1c and weight loss of a low-carb diet in T2D. Reviewed 18 RCTs; 7 studies in quantitative meta-analysis.  | Pooled n=2204 adults with T2D 18 RCTs | 3 months -4 years | **1-year outcomes:**♦ **HBA1c** (10 studies) Low-carb ↓ BG SS in 4 studies. AR range ↓0.02-1.2%; -0.28% WMD. 1 BG SS for control. ♦ **Weight loss** (10 studies) ↓ Low-carb ↓ BG SS in 3 studies.AR range: ↓0.9kg- 7.5kg. 0 studies BG SS for control. Pooled analysis: BG nSS**.** **♦ HDL** (7 studies) Low-carb↑ BG SS in all studies. 0.06mmol/L WMD.**♦TRG** (7 studies) Low-carb ↓ BG SS improved in all studies. -0.24mmol/L WMD..**♦ LDL** (5 studies) BG nSS in all.**♦ Total C** (7 studies) BG nSS in all.**♦ SBP** (7 studies) Low-carb ↓ BG SS in 2 studies. -2.74mg/dL mean difference. No study favored control. **♦ DBP** (7 studies) Low-carb↓ BG SS in 2 studies. No study favored control. Pooled analysis: BG nSS.♦ **Diabetes medication use** In 9 of 14 studies with data, reduction was SS greater with low-carb (insulin, hypoglycemic agents or combined meds score).♦ **Compliance**: Authors concluded that dietary adherence was a problem in most studies reviewed and that <50g carb/day was unrealistic and that <130g carb/day was more achievable. | **Supports claims.** |
| 24 | Ajala O, 201340 | Systematic review and meta-analysis  | Assessed the effect of diet types on glycemic control, lipids, and weight loss. 20 RCTs included. 16 studies included in meta-analysis.Compared low-carbohydrate; vegetarian; vegan; low-glycemic index (GI); high-ﬁber; Mediterranean; high-protein diets vs. control diets (low-fat; high-GI; ADA; European Association for the Study of Diabetes; and low-protein diets).  | n in analyses= 3073 adults T2D20 RCTs | 6 mos-4 years | **Low-carb compared to other diets:****♦ HbA1c** ↓ BG SS -0.12% WMD**♦ Weight** BG nSS **♦ HDL** ↑ BG SS +0.08mmol/L WMD**♦ TRG** BG nSS **♦ LDL** BG nSS  | **Partially supports claims.** |
| 25 | Castañeda-González LM, 2011108  | Systematic review  | Reviewed 8 trials (2000-2010) ≥ 12 weeks duration, to evaluate longer-term effects of low-carb diet compared to low-fat, low-carb Mediterranean diet, usual care diet, healthy eating diet, or low-glycemic index diet. | Adults with T2D8 RCTs | Range: 3-48 months | **♦ HbA1c** 6 studies showed greater reduction with low-carb, 2 BG SS.**♦ Weight** 5 studies showed greater loss with low-carb, 1 BG SS. The longest trial did not show a difference in weight change.**♦ IR** Improved in 1 study.**♦ Lipids** mixed results compared to control. Improved in several studies. | **Limited support for claims.** |
| 26 | Sainsbury E, 2018 109 | Systematic review/meta-analysis | Assessed the effects of carb-restricted diets (≤45%E) compared to high-carb diets (>45%E) on glycemic control in adults with T2D.25 studies. Meta-analyses by diet protocol carb target level (low, moderate, high). | Pooled n=2412 24 studies on T2D; 1 study on T1D |  | **♦ HbA1c** (22 studies): **WG changes:** AR ↓0.77% WG SS (all carb-restricted diets) vs AR ↓0.50% WG SS (high-carb diets)**BG changes:** at 3 mo,WMD -0.47% BG SS (favoring low-carb vs high-carb); BG nSS for mod-carb vs high carb. at 6 mo, WMD -0.36% BG SS (favoring low-carb vs high-carb); BG nSS for mod-carb vs high carb. at 12 and 24 mo, BG nSS **♦ Weight** at 3 mos, WMD -1.08kg (favoring all carb-restricted diets vs high-carb diets). BG SS. All improvement attributed to low-carb diets (AR ↓2.47 kg greater loss than high-carb). at 6 mos, BG nSSat 12 mos WMD -0.58kg (favoring mod-carb vs high-carb) BG SS**♦ Diabetes medication use** (12 studies) Greater reduction on carb-restricted diets at all time points including insulin and oral medications.   | **Supports claims.** |
| 27 | Schwingshackl L, 2018 43 | Systemic review and network meta-analysis | Compared the efficacy of different dietary approaches on glycemic control in T2D. Nine dietary approaches were included low-fat, vegetarian, Mediterranean, high-protein, moderate-carbohydrate, low-carbohydrate, control, low GI/GL, Paleolithic). Lit search through July 2017. 56 trials were included, published between 1978 and 2016.  | Adults with T2D | > 12 weeks | **♦ HbA1c** AR↓0.82% vs control**♦ Fasting glucose** AR↓1.23mmol/L vs control | **Supports claims.** |
|  |  |  |  |  |  |  |  |

**Abbreviations list for Supplementary tables 1-4**:

**T2D**, type 2 diabetes; **BG**, between group; **WG**, within group; **FBG**, fasting blood glucose; **SS**, statistically significant; **nSS**, not statistically significant; **DBP**, diastolic blood pressure; **SBP**, systolic blood pressure; **HDL**, high-density lipoprotein; **TRG**, triglyceride; **DGA**, dietary guidelines for American; **RCT**, randomized controlled trial; **UC**, usual care; **low-carb**, low carbohydrate; **CHO**, carbohydrate; **Med**, Mediterranean; **LDL**, low-density lipoprotein; **BMI**, body mass index; **HOMA-IR**, homeostasis model assessment of insulin resistance; **CVD**, cardiovascular disease; **PBD**, plant based diet; **FU**, follow-up; **VLDL**, very low-density lipoprotein; **LFV**, low-fat vegan; **E**, energy; **GI**, glycemic index; **total C**, total cholesterol; **OB**, obese; **VLCK**, very low calorie ketogenic; **IL-IRa**, interleukin 1-receptor antagonist,: **IL-6**, interleukin-6 **Supplemental Table S5** Standards for reviewing scientific evidence for clinical guidelines

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| System | Link | Year Published | Description | Summary | Focus |
| GRADE | <http://gdt.guidelinedevelopment.org/app/handbook/handbook.html> | 2016 | "Process of rating the quality of the best available evidence and developing health care recommendations following the approach proposed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group"  | "a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations" | Evidence based summaries |
| AGREE II | <https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf> |  | "1. Assess the quality of guidelines; 2. Provide a methodological strategy for the development of guidelines; 3. Inform what information and how information ought to be reported in guidelines." | "developed to address the issue of variability in guideline quality" | Guidelines |
| Guidelines International Network | <http://annals.org/aim/fullarticle/1103747/guidelines-international-network-toward-international-standards-clinical-practice-guidelines> |  | "key components address panel composition, decision-making process, conflicts of interest, guideline objective, development methods, evidence review, basis of recommendations, ratings of evidence and recommendations, guideline review, updating processes, and funding" | "proposed set of key components for guideline development." | Guidelines |
| Institute of Medicine | <http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx> | 2013 | "proposed standards cover a number of elements essential to developing sound practice guidelines, including transparency; conflict of interest; guideline development group composition; CPG– SR intersection; establishing evidence foundations for and strength of recommendations; articulation of recommendations; external review; and updating" | The product of study to "develop a set of standards for developing rigorous, trustworthy clinical practice guidelines." | Clinical Practice Guidelines |

**Supplemental Table S6** Assessment and recommendations for improvement of the ADA guidelines using the National Academies of Sciences, Engineering and Medicine’s *Clinical Practice We Can Trust* evaluation method

|  |  |  |  |
| --- | --- | --- | --- |
| NAM Standard | ADA Report | ADA Critique | Recommendations |
| Standard 1 - Establishing Transparency | "The ADA adheres to the . " | Adherence to National Academy of Medicine Standards not explicitly defined. | Provide a table to ensure National Academy of Medicine Standards 1-7 are adhered to. |
| "The processes by which a CPG is developed and fundedshould be detailed explicitly and publicly accessible. | "Appointment to the PPC is based on excellence in clinical practice and research." | Process not explicitly described. Unknown how the Committee is selected.  | Explicitly describe the process of selection. Publish all nominations and selected committee members before guidelines are published. |
|  | "The ADA funds development of the Standards of Care out of its general revenues and does not use industry support for this purpose." | Funding not explicitly stated. Unknown funding supporting guidelines development | Specify where "general funds" originated and how influence from industry support to ADA activities is minimized. |
| "Strategies for managing potential COI range from exclusion of conflicted members from direct panel participation or restriction of roles, to formal or informal consultation, to participation in certain exclusive recommendations, to simple disclosure of COI." | "All members of the PPC are required to disclose potential conflicts of interest with industry and/or other relevant organizations" | Most members of PPC were conflicted: Only 3/14 on SOC committee had no COI, and only 5/11 on Nutrition Therapy Panel had no COI  | Describe how conflicts amongst members of the review are managed Nam recommends that not more than a minority of members should have a COI so this standard should be upheldEnsure that no funders have COI roles and make this information available |
| Standard 2 - Management of conflict of interest |  |  |  |
| 2.1 Individuals being considered for membership should declare all interests and activities potentially resulting in COI  | "All members of the PPC are required to disclose potential conflicts of interest with industry and/or other relevant organizations. " | Patient and public not obviously involved | Consider COI for membership. State policy |
| 2.2 COI disclosure and discussion | "Members of the committee, their employers, and their disclosed conflicts of interest are listed in the “Professional Practice Committee Disclosures” table" | COI not explicitly considered prior to membership composition | Patient representation from both type1 and type 2 community |
| 2.3 Divestment | None | Divestment policy not stated | Whenever possible guideline development group members should not have COI |
| 2.4 Exclusions | None | Exclusion policy not stated |  |
| Standard 3 - Guideline development group composition |  |  | Compose multidisciplinary & balanced guideline development group, with each component explicitly defined  |
| 3.1 Multidisciplinary & Balanced | “The PPC is a multidisciplinary expert committee comprised of physicians, diabetes educators, registered dietitians, and others who have expertise in a range of areas, including adult and pediatric endocrinology, epidemiology, public health, lipid research, hypertension, preconception planning, and pregnancy care.” | Not uniformly applied | Ensure patient (Type 1 and Type 2)and public involvement by recruiting additional members to the guideline development group. |
| 3.2 Patient & Public Involvement | Unknown | None | "Selection criteria should be applied to choose a consumer representative who can consider the evidence objectively, and make recommendations departing from preconceived views of self or interests" ADA might invite patients or other laypersons to review draft documents or attend a meeting to share perspectives. |
| 3.3 Strategies to increase participation by patient & public |  |  |  |
| Standard 4 - Clinical Practice Guideline–Systematic Review Intersection |  |  |  |
| 4.1. Use systematic reviews that meet IOM standards | Unknown | Unknown |  |
| 4.1. Systematic reviews should coordinate with Guideline Development Review Team | "PPC members systematically searched MEDLINE for human studies related to each section" | No search criteria identified |  |
| 5. Establishing Evidence Foundations for and Rating Strength of Recommendations |  |  |  |
| 5.1. Components: For each recommendation, the following should be provided |  |  |  |
| -- Underlying reasoning | Variable | Not uniformly applied | Define harms/benefits |
| -- Potential Harms/Benefits | Variable | Not uniformly applied | Define relevant available evidence |
| -- Summarize Relevant Available Evidence | Variable | Not uniformly applied | Define quality |
| -- Description of Quality | Variable | Not uniformly applied | Define quantity and consistency |
| -- Description of Quantity and consistency | Variable | Not uniformly applied | Define part played by values, opinion, theory, and clinical experience |
| -- Explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation. | None | Not performed | Uniformly apply rating to level of confidence |
| -- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation | Variable | Not uniformly applied |  |
| 6. Articulation of Recommendations |  |  | Implement standard reporting tools |
| 6.1 Standard reporting: Recommendations should be articulated in a standardized form detailing precisely what the recommended action is, and under what circumstances it should be performed | None | Form not standardized | Define recommendations precisely |
| 6.2 Precise recommendations: Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated. | None | Recommendations not clearly articulated | Implement formal external review  |
| 7. External Review | Unknown. A process to submit comments has been established (“Readers who wish to comment on the 2018 Standards of Medical Care in Diabetes are encouraged to do so. All suggestions will be reviewed by the Association and the Professional Practice Committee.”) | External review not stated | Recruit external reviewers with a full diversity of experiences |
| 7.1 Diversity of experiences: External reviewers should comprise a full spectrum of relevant stakeholders,  | None |  | Develop systems to ensure confidentiality of external reviews |
| 7.2 Confidentiality: The authorship of external reviews submitted by individuals and/or organizations should be kept confidential  | None | Confidentiality of comments is not explicitly assured |  |