

Intake of Nuts or Nut Products Does Not Lead to Weight Gain, Independent of Dietary Substitution Instructions: A Systematic Review and Meta-Analysis of Randomized Trials

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ABSTRACT

Several clinical interventions report that consuming nuts will not cause weight gain. However, it is unclear if the type of instructions provided for how to incorporate nuts into the diet impacts weight outcomes. We performed a systematic review and meta-analysis of published nut-feeding trials with and without dietary substitution instructions to determine if there are changes in body weight (BW) or composition. PubMed and Web of Science were searched through 31 December 2019 for clinical trials involving the daily consumption of nuts or nut-based snacks/meals by adults (≥ 18 y) for >3 wk that reported BW, BMI, waist circumference (WC), or total body fat percentage (BF%). Each study was categorized by whether or not it contained dietary substitution instructions. Within these 2 categories, an aggregated mean effect size and 95% CI was produced using a fixed-effects model. Quality of studies was assessed through the Cochrane risk-of-bias tool. Fifty-five studies were included in the meta-analysis. In studies without dietary substitution instructions, there was no change in BW [standardized mean difference (SMD): 0.01 kg; 95% CI: $-0.07, 0.08$; $I^2 = 0\%$] or BF% (SMD: -0.05% ; 95% CI: $-0.19, 0.09$; $I^2 = 0\%$). In studies with dietary substitution instructions, there was no change in BW (SMD: -0.01 kg; 95% CI: $-0.11, 0.09$; $I^2 = 0\%$); however, there was a significant decrease in BF% (SMD: -0.32% ; 95% CI: $-0.61\%, -0.03\%$; $I^2 = 35.4\%$; $P < 0.05$). There was no change in BMI or WC for either category of studies. Nut-enriched diet interventions did not result in changes in BW, BMI, or WC in studies either with or without substitution instructions. Slight decreases in BF% may occur if substitution instructions are used, but more research is needed. Limitations included varying methodologies between included studies and the frequency of unreported outcome variables in excluded studies. *Adv Nutr* 2021;12:384–401.

Keywords: nuts, tree nuts, energy compensation, energy substitution, body weight, body composition, weight maintenance

Introduction

According to the NHANES, $>40\%$ of Americans are overweight or obese (1). Elevated adiposity increases risk for chronic diseases such as type 2 diabetes (T2D), hypertension, joint problems, and cardiovascular disease (2). Unfortunately, obesity interventions often result in quick weight loss followed by weight regain (3), highlighting the need for effective obesity-prevention methods. To maintain body weight (BW), the 2015–2020 Dietary Guidelines for

Americans recommends consuming a healthy eating pattern in addition to achieving an appropriate energy intake (4). Methods of following a healthy eating pattern include consuming a variety of nutrient-dense foods and to limit foods with excess sugar, sodium, and saturated fat.

Nuts and nut products, although energy dense, are rich sources of fiber, protein, and unsaturated fatty acids, which promote satiety and reduced energy intake (5–7). Numerous randomized controlled trials (RCTs) also report that regular nut consumption, even in large quantities, does not cause weight gain (8–26). However, these studies manipulate the diet or provide instructions on how to incorporate nuts into one's diet to varying degrees, and it is unclear if the type of diet instructions provided to subjects impacts weight and body-composition outcomes. Those different methods include providing no dietary instructions with the nut consumption (8, 10, 11, 13, 21, 24, 25, 27), instructions to

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Supplemental Figures 1 and 2 are available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at <https://academic.oup.com/advances>.

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Abbreviations used: BF%, total body fat percentage; BW, body weight; ES, effect size; ICC, interclass correlation coefficient; Fail-Safe N, Fail-Safe Number; RCT, randomized controlled trial; SMD, standardized mean difference; T2D, type 2 diabetes; WC, waist circumference.

substitute energy-equivalent foods or specific macronutrients in their typical diet for the nuts provided (14–20, 28–31), or the provision of all meals in an outpatient feeding setting designed to keep participants in energy balance (32–37).

To date, only 2 long-term nut trials (>8 wk) have compared adiposity measures in participants who received diet substitution instructions (isocaloric substitution) versus those who did not receive instructions, and BW or body composition was significantly influenced by the type of dietary instruction that was provided (38, 39). A recent meta-analytic review of weight change with nut-enriched clinical trials did not consider the effect of varying dietary substitution instructions (40). Therefore, we systematically reviewed and performed a meta-analysis of clinical trials with parallel or crossover designs to examine the impact of no dietary substitution instructions or some type of dietary substitution instructions on BW and body composition during interventions lasting >3 wk in adults. We hypothesized that studies without substitution instructions would result in a significant increase in BW, BMI, waist circumference (WC), and total body fat percentage (BF%), while studies with energy- or fat-substitution instructions would not result in changes in these aforementioned outcome variables.

Methods

Search strategy

This work was completed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (41). A systematic search identified clinical trials measuring changes in BW or body composition during nut interventions. Eligible studies were identified by searching PubMed and Web of Science databases from inception through 31 December 2019. The following search terms were used: (“nut” OR “walnut” OR “peanut” OR “hazelnut” OR “almond” OR “pistachio” OR “cashew” OR “macadamia” OR “pecan” OR “pine nut” OR “brazil nut” OR “tree nut” OR “mixed nut”) AND (“metabolic syndrome” OR “Mets” OR “overweight” OR “weight gain” OR “obesity” OR “obese” OR “adiposity” OR “adipose” OR “body weight” OR “body mass index” OR “BMI” OR “waist circumference” OR “hypertension” OR “blood pressure” OR “hypercholesterolemia” OR “dyslipidemia” OR “cholesterol” OR “triglycerides” OR “diabetes” OR “glucose” OR “glycemia” OR “WHR” OR “weight loss” OR “body fat”). Full-text studies that were published in English were considered.

Inclusion and exclusion criteria

To be included in the meta-analysis, the studies had to be peer-reviewed, published in English, and containing a parallel or crossover design. In addition, the studies needed to compare a nut-containing diet with a control diet in adults and report 1 of the following outcomes: BW, BMI, WC, or BF%. More specifically, interventions that involved the consumption of nuts alone, within snack bars, or part of a meal were included. All studies in adult populations were included regardless of disease state, gender, or age range. The minimum duration and dosage of the intervention

were ≥ 3 wk and ≥ 10 g/d for 5 d/wk, respectively. When there were multiple published manuscripts on the same dataset, the paper with the longest follow-up period was selected. If the outcome data were not published in the manuscript, researchers contacted the corresponding author to obtain required data. Exclusion criteria were the following: 1) reviews, editorials, nonresearch letters; 2) BW data not available; 3) BW was measured frequently and highly controlled, such as daily self-weighing; 4) lack of comparator diet; 5) comparator diet consumed another nut or nut butter; 6) controlled-feeding trials in which all meals were provided; 7) studies using animal models; and 8) intentional weight loss or gain was used. The study selection process is illustrated in Figure 1.

Data collection

Following the systematic search of PubMed and Web of Science, individual studies were screened based on the title and abstracts for inclusion or exclusion criteria. Next, studies entered full-text review. Studies that met the inclusion criteria during the full-text review were included in the systematic review and meta-analysis. Two reviewers collected the study details (study author, publication year, study design, baseline age, baseline BMI, dosage of nuts, type of comparator diet, type of diet instructions, length of intervention, whether or not weight loss/gain was the purpose of the study). Interclass correlation coefficients (ICCs) for absolute agreement were calculated to examine interrater reliability for BW, BMI, WC, and BF%, and any discrepancies between reviewers were resolved. Additionally, the quality of each study was assessed using the Cochrane risk-of-bias tool for RCTs (42).

All studies were categorized as either containing substitution instructions or not containing substitution instructions. A study was categorized as containing no substitution instructions if the nut intervention group did not receive specific instructions on how to incorporate the provided nuts into their usual diet. A study was categorized as containing substitution instructions if the nut intervention group received specific instructions on how to incorporate the nuts into the diet. For example, if subjects were instructed to substitute energy-equivalent foods habitually consumed in the diet for the added nuts (i.e., isocaloric substitution), the study was categorized as containing substitution instructions.

Statistical methods

The primary outcome was the standardized mean difference (SMD) in BW, BMI, WC, and BF% between subjects consuming nut-containing and control diets. For parallel studies, Cohen's *d* effect sizes (ESs) were calculated by subtracting the mean change in weight during the control group from the mean change in weight during the nut intervention; then, this difference was divided by the pooled pre-test SD (43–45). A positive ES value indicated a less favorable change occurred in the intervention group compared with the control group. For crossover studies, all measurements from the intervention period and all measurements from

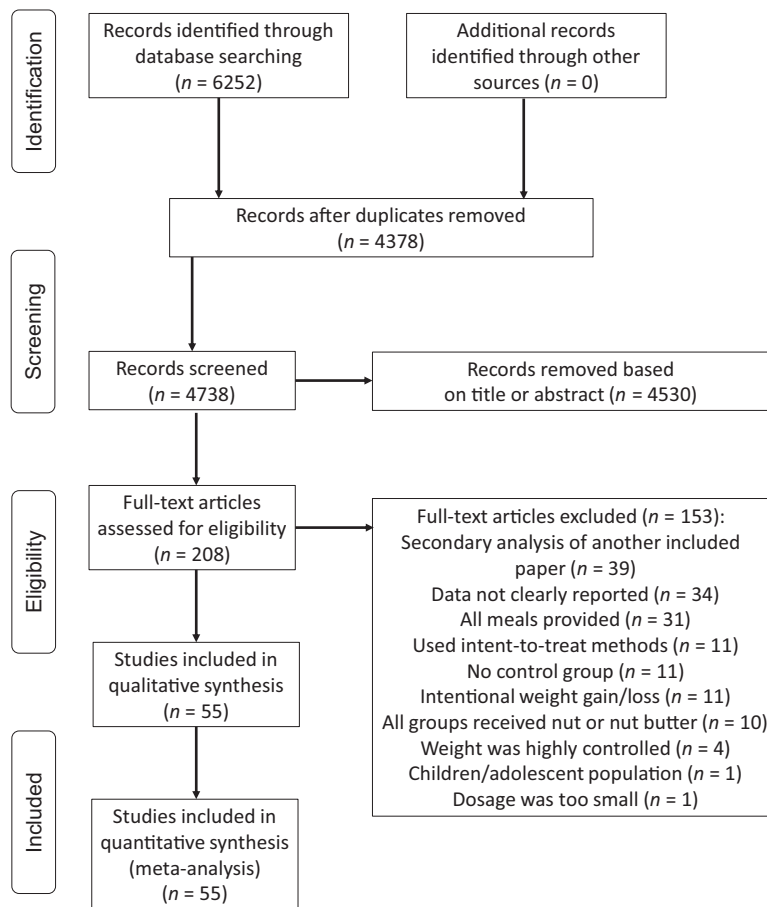


FIGURE 1 PRISMA flowchart. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

the control period were incorporated into the ES calculation, similar to the calculation for parallel trials. This methodology is a conservative estimate and reduces the statistical power of crossover studies to show an effect (46). Furthermore, to avoid unit-of-analysis error, in studies that contained >1 nut intervention group and a control group, the intervention groups were combined to develop 1 ES for the study. For example, if an intervention contained almond, walnut, and control groups, then the sample size, mean, and SDs of the almond and walnut groups were combined using the formulas recommended by the Cochrane Collaboration Handbook (47). Finally, the new calculations for the sample size, mean, and SD of the intervention group were incorporated into the ES calculation for the study.

Aggregated mean ESs and 95% CIs were calculated for studies with and without substitution instructions using a fixed-effects model because homogeneity was shown. The DerSimonian and Laird estimator was used to quantify heterogeneity (48), which was indicated if the Q total reached a significance level of $P < 0.05$ (43). Heterogeneity was also measured using the I^2 statistic (49). Low, moderate, or high heterogeneity was categorized as values of 25%, 50%, and 75% for the I^2 statistic, respectively. Possible bias was evaluated using Egger's test (it assesses whether the variation in the ES is due to publication bias) and funnel plots that plotted the SE against the ES. Fail-Safe Number

(Fail-Safe N_+), which estimates the number of additional null effects of average sample size needed to overturn the observed significant effect, was calculated for all significant effects using Rosenberg's method (50). Statistical analyses were performed with R version 3.6.2 (The R Foundation, Vienna, Austria). A couple of sensitivity analyses were used to determine if the meta-analysis findings are robust to the decisions made when determining the inclusion and exclusion criteria (47). The first sensitivity analysis removed all effects in which the control group received a dietary intervention (e.g., a biscuit containing the same energy as provided in the nut group). These studies were originally categorized based on whether or not the intervention group received dietary substitution instructions; thus, studies were removed from both categories during the sensitivity analysis. The second sensitivity analysis removed all crossover studies.

Results

Study selection

The database search yielded 6252 results, and 1874 duplicates were removed. We excluded 4530 studies based on titles and abstracts and 153 after a full-text review. Fifty-five clinical trials published between 1997 and 31 December 2019 were included in the final meta-analysis (9, 11, 13, 17, 18, 24, 25, 32, 51–97) (Table 1). There were 52 effects for BW, 36 effects for

TABLE 1 Characteristics of included clinical trials involving nut consumption with and without substitution instructions in adults¹

First author, year (ref), country	Study design	Subjects in analysis, n	Population	Average age, y	Diet period, wk	Type of nut	Dose of nut	Nut diet	Instructions?	Control diet	Risk of bias
Abbaspour et al., 2019 (51), USA	Parallel	48	Overweight/obese	Not reported	8	Mixed nuts	42.5 g/d	Habitual diet	No	Habitual diet + pretzels	Some concerns
Agebratt et al., 2016 (52), Sweden	Parallel	30	Healthy	24	8	Mixed nuts	7 kcal/kg body weight	Habitual diet	No	Habitual diet + isocaloric fruit	Some concerns
Bashan et al., 2018 (53), Turkey	Parallel	49	Dyslipidemia	41	12	Walnut	45 g/d	AHA recommendations	Yes	AHA recommendations	Some concerns
Bento et al., 2014 (24), Brazil	Crossover	20	Mildly high cholesterol	35	6	Almond	20 g/d	Habitual diet	No	Habitual diet + placebo	Some concerns
Bitok et al., 2018 (54), USA and Spain	Parallel	307	Healthy	69	24	Walnuts	~15% of caloric needs	Habitual diet	No	Habitual diet	Low
Burns-Whitmore et al., 2014 (91), USA	Crossover	21	Healthy	38	42	Walnut	284 g/d	Habitual diet	No	Habitual diet + standard egg	Low
Canudas et al., 2019 (55), Spain	Crossover	49	Prediabetes	56	16	Pistachio	57 g/d	Habitual diet	No	Habitual diet + energy intake was adjusted to compensate for lack of pistachios	Low
Carughi et al., 2019 (56), France	Parallel	60	Healthy women	35	4	Pistachio	56 g/d	Habitual diet + pistachios as afternoon snack	No	Habitual diet + biscuit as afternoon snack	Some concerns
Casas-Agustench et al., 2011 (57), Spain	Parallel	50	Metabolic syndrome	52	12	Mixed nuts	30 g/d	General health diet	No	General healthy diet	Some concerns
Chisholm et al., 2005 (58), New Zealand	Crossover	28	Healthy	48	6	Mixed nuts	30 g/d	Low-fat background diet + self-selected nuts	Yes	Instructions background diet + canola oil	Low
Cohen and Johnston, 2011 (59), USA	Parallel	13	T2D	66	12	Almonds	28 g/d	Habitual diet	No	Habitual diet + containing cereal cheese	Some concerns

(Continued)

TABLE 1 (Continued)

First author, year (ref), country	Study design	Subjects in analysis, n	Population	Average age, y	Diet period, wk	Type of nut	Dose of nut	Nut diet	Instructions?	Control diet	Risk of bias
Damascono et al., 2011 (9), Spain ²	Crossover	36	Mildly high cholesterol	56	4	Walnuts or almonds	22% of energy intake	Background Mediterranean diet	Yes	Background Mediterranean diet + olive oil	High
Damavandi et al., 2013 (60), Iran	Parallel	48	T2D	56	8	Hazelnut	10% of energy intake	Habitual diet	Yes	Habitual diet	Some concerns
Damavandi et al., 2019 (61), Iran	Parallel	43	T2D	54	8	Cashews	10% of energy intake	Habitual diet	Yes	Habitual diet	Some concerns
Davidi et al., 2011 (62), USA	Parallel	94	Overweight	54	8	KIND (KIND, LLC) fruit and nut bars	2 bars/d	Habitual diet	No	Habitual diet	Some concerns
de Souza et al., 2018, (63), Brazil	Parallel	46	Overweight/obese women	Not reported	8	Almond	20 g/d	Prescribed individualized normocaloric diet	Yes	Prescribed individualized normocaloric diet	Some concerns
Dhillon et al., 2018 (64), USA	Parallel	73	Healthy college freshmen	18	8	Almond	56.7 g/d	Habitual diet	No	Habitual diet + isocaloric graham cracker	Some concerns
Eastman and Clayshulte, 2005 (94), USA	Parallel	44	Hyperlipidemia	46	8	Pecan	68 g/d	Habitual diet	No	Habitual diet	High
Fantino et al., 2019 (65), France	Parallel	58	Premenopausal women	32	12	Pistachio	44 g/d	Habitual diet + pistachios as midmorning snack	No	Habitual diet	Some concerns
Gulati et al., 2014 (66), India	Parallel	68	Metabolic syndrome	42	24	Pistachio	20% of energy intake	General healthy diet	Yes	General healthy diet	Some concerns
Hernández-Alonso et al., 2014 (67), Spain	Crossover	54	Prediabetes	55	12	Pistachio	57 g/d	Prescribed diet designed to meet energy needs	Yes	Prescribed diet designed to meet energy needs + instructions to eat extra foods containing fat to account for lack of nuts	High

(Continued)

TABLE 1 (Continued)

First author, year (ref), country	Study design	Subjects in analysis, n	Population	Average age, y	Diet period, wk	Type of nut	Dose of nut	Nut diet	Instructions?	Control diet	Risk of bias
Hiraoka-Yamamoto et al., 2004 (68), Japan	Parallel	47	Healthy	19	3	Macadamia nut	10 g/d	Habitual diet + bread containing macadamia nuts	No	Habitual diet + bread containing butter	Some concerns
Hollis and Mattes, 2007 (32), USA	Crossover	20	Healthy	24	10	Almonds	58 g/d	Habitual diet	No	Habitual diet	Some concerns
Hwang et al., 2019 (95), South Korea	Crossover	84	Metabolic syndrome	39	16	Walnuts	45 g/d	Habitual diet	No	Habitual diet	Low
Jamshed et al., 2015 (25), Pakistan ²	Parallel	150	CAD	60	12	Pakistani or American almond	10 g/d	Habitual diet	No	Habitual diet	Some concerns
Jenkins et al., 2018 (89), Canada ²	Parallel	117	T2D	33	12	Mixed nut (half or full dose)	474 kcal per 2000-kcal diet needs provided as half dose of mixed nut and half muffin or full dose of mixed nut	Background NCEP ATP III diet and ADA dietary advice	Yes	Background NCEP ATP III and ADA dietary advice + muffin with no nuts	Some concerns
Jenkins et al., 2002 (69), Canada ²	Crossover	81	Dyslipidemia	64	4	Almonds	73 g/d or 37 g/d in muffin	Background NCEP Step 2 diet	Yes	Background NCEP Step 2 diet + muffin with no nuts	Some concerns
Jung et al., 2018 (70), Korea	Crossover	84	Overweight	52	4	Almonds	56 g/d	Habitual diet	No	Habitual diet + isocaloric cookie	Low
Kasiwal et al., 2015 (71), India	Parallel	42	Dyslipidemia	39	12	Pistachio	40 g/d	ADA exercise and diet counseling	Yes	ADA exercise and diet counseling	Some concerns
Katz et al., 2012 (96), USA	Crossover	46	Overweight adults	57	8	Walnuts	56 g/d	Habitual diet	Yes	Habitual diet	Low
Kocoyigit et al., 2006 (93), Turkey	Parallel	44	Healthy	33	3	Pistachio	20% of energy intake	Habitual diet	Yes	Habitual diet	Some concerns

(Continued)

TABLE 1 (Continued)

First author, year (ref), country	Study design	Subjects in analysis, n	Population	Average age, y	Diet period, wk	Type of nut	Dose of nut	Nut diet	Instructions?	Control diet	Risk of bias
Lee et al., 2014 (72), South Korea	Parallel	60	Metabolic syndrome	Not reported	6	Mixed nuts	30 g/d	Habitual Diet	No	Habitual diet	Some concerns
Liu et al., 2017 (73), Korea ²	Parallel	169	Healthy	26	16	Almonds consumed as premeal snack or between meals	56 g/d	Habitual diet	No	Habitual diet + isocaloric cookie	High
Ma et al., 2010 (17), USA	Crossover	24	T2D	58	8	Walnuts	56 g/d	Habitual diet	Yes	Habitual diet	Low
Mercanligil et al., 2007 (74), Turkey	Crossover	15	Hypercholesterolemic men	48	4	Hazelnut	40 g/d	Low-fat, low-cholesterol, and high-carbohydrate diet	No	Low-fat, low-cholesterol, and high-carbohydrate diet	High
Mohan et al., 2018 (75), India	Parallel	269	T2D	21	12	Cashew	30 g/d	Diabetic diet	Yes	Diabetic diet	Some concerns
Morgan and Clayshulte, 2000 (11), USA	Parallel	19	Healthy	41	8	Pecan	68 g/d	Habitual diet	No	Habitual diet	Some concerns
Nijke et al., 2017 (76), USA	Parallel	32	Overweight	58	12	KIND bars	1–4 bars/d	Habitual diet	Yes	Habitual diet	Some concerns
Nouran et al., 2010 (77), Iran	Crossover	54	Hypercholesterolemic men	43	4	Peanuts	20% of energy	Habitual diet	No	Habitual diet	Some concerns
O'Byrne et al., 1997 (78), USA	Parallel (quasi-experimental)	25	Hypercholesterolemic women	Not reported	24	Peanut	35–68 g/d	Prescribed low-fat diet	Yes	Habitual low-fat diet	High
Olmedilla-Alonso et al., 2008 (79), Spain	Crossover	25	High CVD risk	54	5	Walnut-enriched restructured meats	19.4 g/d	Consumed walnut-enriched meats + avoided all other meats	Yes	Consumed restructured meats without walnuts + avoided all other meats	Low

(Continued)

TABLE 1 (Continued)

First author, year (ref), country	Study design	Subjects in analysis, n	Population	Average age, y	Diet period, wk	Type of nut	Dose of nut	Nut diet	Instructions?	Control diet	Risk of bias
Palacios et al., 2019 (90), USA	Crossover	33	Prediabetes	48	6	Almond	84 g/d	Habitual diet	Yes	Habitual diet	High
Razquin et al., 2010 (92), Spain	Parallel	435	High CVD risk	68	156	Mixed nuts	30 g/d	Mediterranean diet	No	Low-fat diet	High
Ros et al., 2004 (80), Spain	Crossover	21	Moderate hypercholesterolemia	55	4	Walnut	18% of energy intake	Background Mediterranean diet	Yes	Background Mediterranean diet	High
Ruisinger et al., 2015 (81), USA	Parallel	48	On statin therapy	60	4	Almonds	100 g/d	Background TLC diet	Yes	Background TLC diet	Some concerns
Salas-Huetos et al., 2018 (82), Spain	Parallel	98	Healthy men	25	14	Mixed nuts	60 g/d	Habitual diet	No	Habitual diet	Some concerns
Spiller et al., 1998 (83), USA	Parallel	30	Hypercholesterolemia	53	4	Almonds	100 g/d	Prescribed background diet of whole and unrefined foods	No	Prescribed background diet of whole and unrefined foods + Cheddar cheese	Some concerns
Sweazea et al., 2014 (84), USA	Parallel	21	T2D	56	12	Almond	43 g (5–7 times/wk)	Habitual diet	No	Habitual diet	Some concerns
Tan et al., 2013 (13), Australia ²	Parallel	137	Increased T2D risk	29	4	Almond	43 g/d	No instructions or instructions to consume almonds at breakfast, lunch, morning snack, or afternoon snack	No	Habitual diet	Some concerns
Tapsell et al., 2004 (85), Australia	Parallel	38	T2D	60	24	Walnut	30 g/d	Low-fat diet	Yes	Low-fat diet	Some concerns
Tapsell et al., 2009 (18), Australia	Parallel	35	Non-insulin-dependent T2D	54	52	Walnut	30 g/d	Low-fat diet	Yes	Low-fat diet	Some concerns

(Continued)

TABLE 1 (Continued)

First author, year (ref), country	Study design	Subjects in analysis, n	Population	Average age, y	Diet period, wk	Type of nut	Dose of nut	Nut diet	Instructions?	Control diet	Risk of bias
Tey et al., 2013 (86), New Zealand ²	Parallel	107	Overweight/obese	42	12	Hazelnut	30 or 60 g/d	Habitual diet	No	Habitual diet	Some concerns
Tey et al., 2011 (97), New Zealand	Parallel	61	Healthy adults	38	12	Hazelnut	42 g/d	Habitual diet	No	Habitual diet	Some concerns
Wu et al., 2010 (87), China	Parallel	189	Metabolic syndrome	48	12	Almond	30 g/d	AHA diet instructions	Yes	AHA diet instructions	Some concerns
Zaveri et al., 2009 (88), UK	Parallel	23	Healthy men	41	12	Almond	56 g/d	General healthy advice	No	Prescribed American background diet	High

¹ADA, American Diabetes Association; AHA, American Heart Association; ATP III, Adult Treatment Program III; CAD, coronary artery disease; CVD, cardiovascular disease; NCEP, National Cholesterol Education Program; ref, reference; T2D, type 2 diabetes; TLC, therapeutic lifestyle changes.

²Denotes study in which ≥ 2 intervention groups were combined to calculate the overall effect size for the study.

BMI, 27 effects for WC, and 19 effects for BF%. Seven studies contained ≥ 1 nut intervention groups (9, 13, 25, 69, 73, 86, 89), which were combined to create 1 overall ES for the study. There were 3811 subjects represented in interventions that maintained a mean duration of 13.8 ± 21.5 wk and dosage of 48.2 ± 20.8 g nuts/d. Study populations included individuals with normal weight/healthy, overweight/obese, hypercholesterolemia, metabolic syndrome, prediabetes, T2D, and elevated cardiovascular disease or T2D risk. The nut interventions included almonds, cashews, hazelnuts, macadamia nut, mixed nut, peanut, pecan, pistachio, walnut, and a nut-based snack bar. **Table 2** describes the characteristics of studies with and without substitution instructions. In studies where participants received substitution instructions, those instructions included the following: substituting energy (kilocalories) from habitual diet or prescribed background diet (17, 53, 63, 67, 75, 76, 81, 89, 90, 96), substituting fat energy (18, 60, 61, 66, 93), substituting starchy foods (69, 87) or meat sources (79), substituting a combination of foods or macronutrients (71, 78), substituting specific food items recommended in a background diet (9, 80), or substituting specific foods based on individualized advice or exchange lists (58, 85).

Meta-analysis of nut intake and changes in adiposity

An overview of the meta-analysis results is presented in **Table 3**. In studies without substitution instructions, there was no significant effect of the intervention on BW (SMD: 0.01 kg; 95% CI: $-0.07, 0.08$; $I^2 = 0\%$), BMI (in kg/m^2) (SMD: 0.01; 95% CI: $-0.08, 0.11$; $I^2 = 0\%$), WC (SMD: 0.01 cm; 95% CI: $-0.09, 0.10$; $I^2 = 0\%$), or BF% (SMD: -0.05% ; 95% CI: $-0.19\%, 0.09\%$; $I^2 = 0\%$) (**Figures 2A, 3A, 4A, and 5A**). Similarly, in studies with substitution instructions, there was no significant effect of the intervention on BW (SMD: -0.01 kg; 95% CI: $-0.11, 0.09$; $I^2 = 0\%$), BMI (SMD: 0.00; 95% CI: $-0.12, 0.13$; $I^2 = 0\%$), or WC (SMD: 0.01 cm; 95% CI: $-0.11, 0.13$; $I^2 = 0\%$) (**Figures 2B, 3B, 4B**). There was a significant effect of the intervention on BF% in studies that used substitution instructions (SMD: -0.32% ; 95% CI: $-0.61\%, -0.03\%$; $I^2 = 35.4\%$; $P < 0.05$) (**Figure 5B**).

Rater agreement

The ICC for all effects was ≥ 0.85 (**Table 3**). The ICC increased to 100% after adjusting for discrepancies between reviewers.

Homogeneity of results

For studies without substitution instructions, there was no heterogeneity for BW ($Q = 6.24$; $P = 1.00$; $I^2 = 0.0\%$), BMI ($Q = 3.58$; $P = 1.00$; $I^2 = 0.0\%$), WC ($Q = 3.28$; $P = 1.00$; $I^2 = 0.0\%$), and BF% ($Q = 3.58$; $P = 1.00$; $I^2 = 0.0\%$) (**Table 3**). Similarly, for studies with substitution instructions, there was no or moderate heterogeneity for BW ($Q = 1.87$; $P = 1.00$; $I^2 = 0.0\%$), BMI ($Q = 1.52$; $P = 1.00$; $I^2 = 0.0\%$), WC ($Q = 2.04$; $P = 1.00$; $I^2 = 0.0\%$), and BF% ($Q = 6.19$; $P = 0.19$; $I^2 = 35.4\%$) (**Table 3**). Due to the lack of significant heterogeneity among all outcome variables, a fixed-effects model was used in all analyses.

TABLE 2 Characteristics of nut trials included in meta-analysis with and without substitution instructions in adults¹

	Effect sizes from studies without instructions (n = 36)	Effect sizes from studies with instructions (n = 28)
Age, y	41.7 ± 14.4	49.8 ± 10.8
Nut dose, g/d	47.6 ± 19.7	49.1 ± 22.6
Intervention duration, wk	15.4 ± 27.1	11.8 ± 10.6
Effect sizes from studies with dietary intervention in control group, % (n)	32.3 (10)	25.0 (6)
Almond, % (n)	35.5 (11)	20.8 (5)
Cashew, % (n)	0 (0)	8.3 (2)
Hazelnut, % (n)	9.7 (3)	4.2 (1)
Nut-based bar, % (n)	3.2 (1)	4.2 (1)
Macadamia nut, % (n)	3.2 (1)	0 (0)
Mixed nut, % (n)	19.4 (6)	8.3 (2)
Peanut, % (n)	3.2 (1)	4.2 (1)
Pecan, % (n)	6.5 (2)	0 (0)
Pistachio, % (n)	9.7 (3)	16.7 (4)
Walnut, % (n)	9.7 (3)	33.3 (8)

¹All values are means ± SDs unless otherwise indicated.

Fail safe N and publication bias

The fail-safe N for effects with substitution instructions that reported BF% was $N_+ = 5$ using the Rosenberg method (50). For studies with and without diet instructions, visual inspections of the funnel plots showed reasonable symmetry (Supplemental Figures 1 and 2). Additionally, in studies without substitution instructions, Egger's tests indicated no publication bias for all outcomes (BW: $P = .56$; BMI: $P = 0.84$; WC: 0.74; and BF%: $P = 0.63$) (Table 3). Egger's tests also indicated no publication bias in studies with substitution instructions for all outcomes except for BW and BMI (BW: $P = 0.03$; BMI: 0.03; WC: 0.56; BF%: 0.28).

Sensitivity analysis

In the first sensitivity analysis, all effects in which the control group received a dietary intervention were removed (9, 51, 52, 56, 58, 59, 64, 69, 70, 76, 79, 83, 90, 95, 98) (such as the isocaloric equivalent food described above in Methods), and the results are presented in Table 4. For studies with substitution instructions that reported on BF%, there was no longer a significant effect of the interventions and there was no heterogeneity (SMD: -0.18% ; 95% CI: -0.51% , 0.14% ; $I^2 = 0\%$). All other outcomes remained nonsignificant and homogeneous.

In the second sensitivity analysis, all effects from studies with crossover designs were removed (9, 17, 24, 32, 55, 58, 67, 69, 70, 74, 77, 79, 80, 90, 91, 95, 96), and the results are presented in Table 5. The results of this sensitivity analysis did not significantly differ from the main analysis. All outcomes remained nonsignificant and homogeneous, except for the aggregated effect of the intervention on BF% in studies with substitution instructions (SMD: -0.32% ; 95% CI: -0.61% , -0.03% ; $I^2 = 35.4\%$), which was also significant with moderate heterogeneity in the main analysis.

Discussion

This was the first meta-analysis to separately investigate the impact of nut-enriched diets with and without dietary substitution instructions on BW and body-composition outcomes. Based on the studies included in the meta-analysis, nut consumption does not result in changes in BW, BMI, or WC, independent of whether or not substitution instructions are provided. Conversely, nut consumption may result in decreased BF% when substitution instructions are used, but these results should be interpreted with caution as described in more detail below. Our analysis did not directly compare whether or not providing dietary substitution instructions is more or less favorable for BW or body-composition

TABLE 3 Overview of meta-analysis results of nut trials with and without dietary substitution instructions in adults¹

Outcome variable	Substitution instruction?	n	SMD (95% CI)	I^2 , %	P	Egger's test	ICC	Mean difference
Weight, kg	No	29	0.01 (−0.07, 0.08)	0	0.88	0.56	0.94	0.13
	Yes	23	−0.01 (−0.11, 0.09)	0	0.82	0.03	—	−0.26
BMI, kg/m ²	No	21	0.01 (−0.08, 0.11)	0	0.80	0.84	0.94	0.04
	Yes	15	0.00 (−0.12, 0.13)	0	0.95	0.03	—	0.00
Waist circumference, cm	No	16	0.01 (−0.09, 0.10)	0	0.85	0.74	0.99	0.16
	Yes	11	0.01 (−0.11, 0.13)	0	0.86	0.56	—	−0.22
Total body fat, %	No	14	−0.05 (−0.19, 0.09)	0	0.45	0.63	0.85	−0.31
	Yes	5	−0.32 (−0.61, −0.03)	35.4	0.03	0.28	—	−1.86

¹ICC, interclass correlation coefficient; SMD, standardized mean difference.

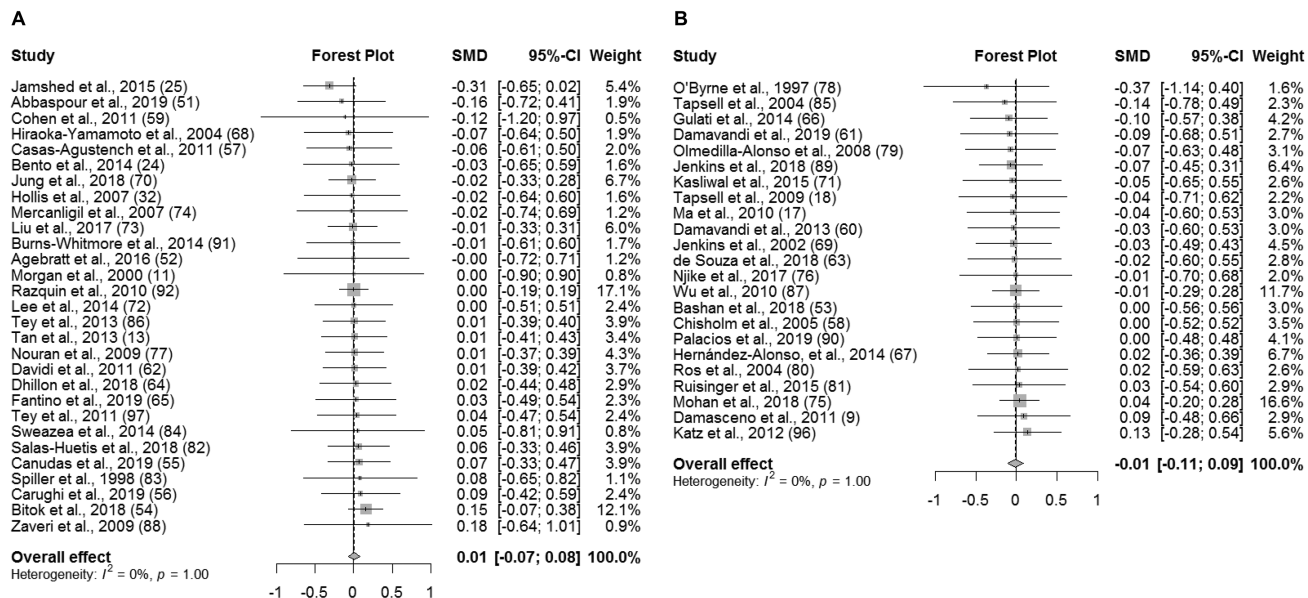


FIGURE 2 Forest plot of BW (kg) for studies without dietary substitution instructions (A) and BW for studies with dietary substitution instructions (B). For each individual study, the square represents the SMD in BW between the intervention and control groups. The area of the square is proportional to the weight. Horizontal lines represent 95% CIs. BW, body weight; SMD, standardized mean difference.

outcomes because each category of studies was analyzed in a separate model. The decision to maintain separate models for the 2 categories of studies was made a priori in an effort to most effectively answer the research question.

As mentioned above, one interesting finding from the present meta-analyses is that daily nut consumption may result in decreases in BF% if substitution instructions are used; however, these results should be interpreted with caution. Only 5 studies were included in the meta-analysis of studies involving substitution instructions that reported BF%, and a variety of methods were used to measure

BF%, including DXA, bioelectrical impedance, and skinfold-thickness measurements. The variability in precision and accuracy among these methods for measuring body composition should be considered when interpreting these results. In addition, the significant effect may have been driven by 1 study in particular (76). In the study by Njike et al. (76), the intervention group ate a nut-based snack bar and the control group ate a conventional snack food for 12 wk. The intervention group lost 1.7% of body fat and the control group gained 6.2% of body fat, resulting in a negative ES that was driven by the increase in adiposity in

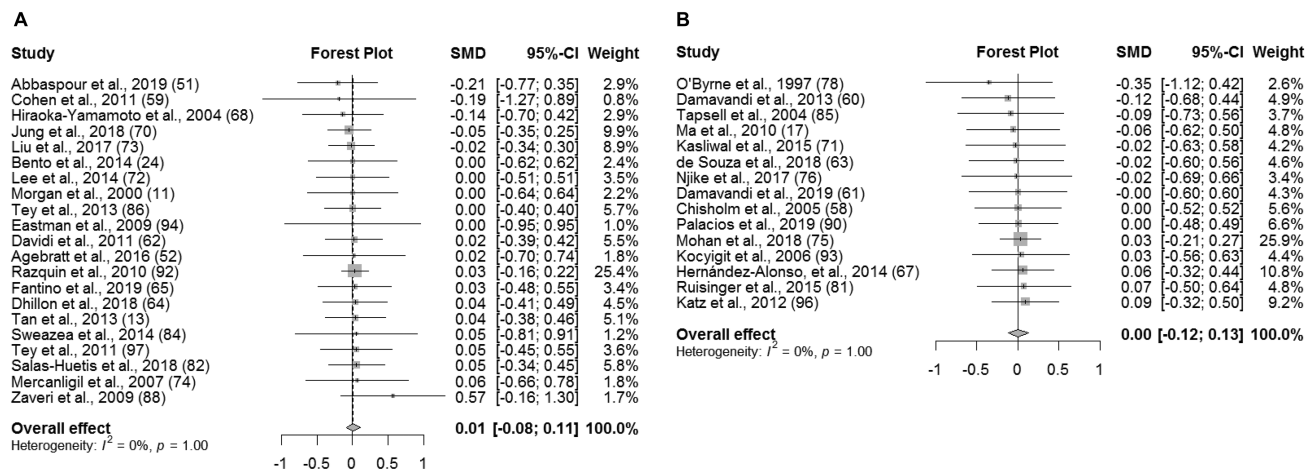


FIGURE 3 Forest plot of BMI (kg/m²) for studies without dietary substitution instructions (A) and BMI for studies with dietary substitution instructions (B). For each individual study, the square represents the SMD in BMI between the intervention and control groups. The area of the square is proportional to the weight. Horizontal lines represent 95% CIs. SMD, standardized mean difference.

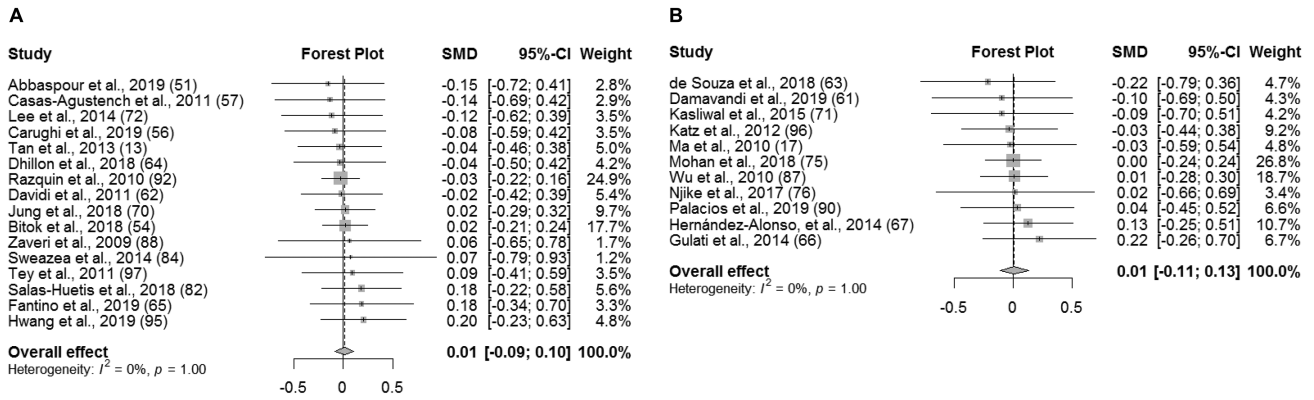


FIGURE 4 Forest plot of WC (cm) for studies without dietary substitution instructions (A) and WC for studies with dietary substitution instructions (B). For each individual study, the square represents the SMD in WC between the intervention and control groups. The area of the square is proportional to the weight. Horizontal lines represent 95% CIs. SMD, standardized mean difference.

the control group. During the first sensitivity analysis, this study was removed since the control group had also received a dietary intervention. As a result, the significant effect of the interventions on BF% was lost, and the heterogeneity was reduced from 35.4% to 0.0%.

Finding no change in outcome measures for studies with or without substitution instructions was somewhat surprising and contrary to our hypothesis. We had originally thought that studies without some type of dietary substitution instruction for the daily nut consumption would result in increased BW, BMI, WC, or BF%. This hypothesis was based on 2 previous clinical nut trials that directly compared the impact of varying dietary substitution instructions on weight and body-composition outcomes (38, 39). In those studies, weight or body composition was significantly influenced by the type of dietary instructions provided; yet, our meta-analysis results indicate that weight change does not occur with or without dietary substitution instructions. For the studies without substitution instructions in our analysis, the mean duration was 15.4

wk and the mean dosage was ~47.8 g/d, providing ~300 calories (99). According to the NIH body weight planner (100), an individual with a BMI of 30 would gain 3.3 kg without dietary compensation when consuming 47.8 g/d of mixed nuts for 16 wk. Since the meta-analysis showed that weight gain does not occur in studies with or without substitution instructions, there must be physiological mechanisms in place that prevent changes in weight during nut interventions without substitution instruction. Previous studies have explored possible mechanisms that allow weight maintenance with nut consumption, and they include increased satiety (101, 102) and subsequent reduced energy intake (13, 103), decreased bioavailability (104–107), increased diet-induced thermogenesis (108–110), and/or increased resting metabolic rate (39, 52). More clinical studies that directly compare the impact of interventions with and without dietary substitution instructions, and studies that investigate the mechanisms for weight maintenance with tree nut consumption, are needed to fully elucidate our hypothesis.

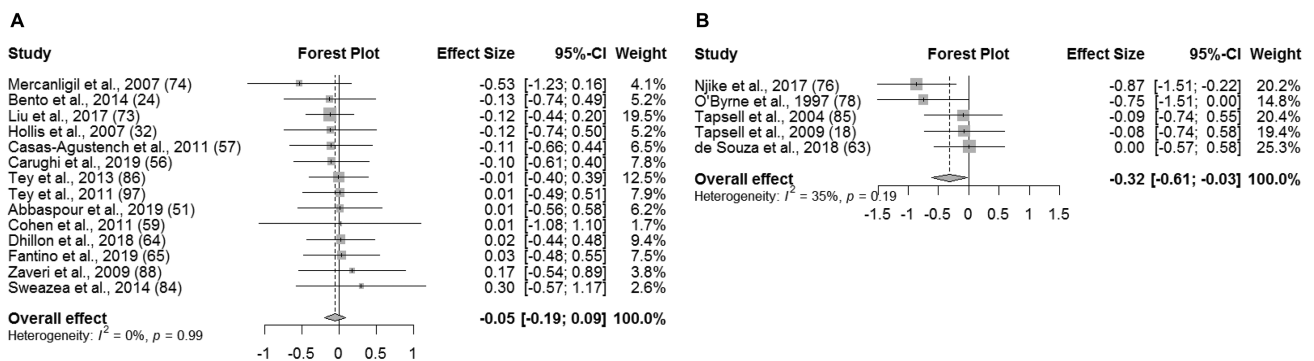


FIGURE 5 Forest plot of total BF% for studies without dietary substitution instructions (A) and BF% for studies with dietary substitution instructions (B). For each individual study, the square represents the standardized mean difference (SMD) in BF% between the intervention and control groups. The area of the square is proportional to the weight. Horizontal lines represent 95% confidence intervals. BF%, body fat percentage; SMD, standardized mean difference.

TABLE 4 Overview of results from sensitivity analysis in clinical trials involving nut consumption in adults¹

Outcome variable	Substitution instruction?	n	SMD (95% CI)	I ² , %	P	Egger's test
Weight, kg	No	20	0.01 (−0.08, 0.10)	0	0.78	0.68
	Yes	17	−0.01 (−0.12, 0.10)	0	0.82	0.03
BMI, kg/m ²	No	14	0.04 (−0.07, 0.16)	0	0.48	0.37
	Yes	12	0.01 (−0.13, 0.14)	0	0.94	0.05
Waist circumference, cm	No	11	0.01 (−0.10, 0.12)	0	0.88	0.50
	Yes	9	0.01 (−0.12, 0.14)	0	0.89	0.53
Total body fat, %	No	9	−0.04 (−0.23, 0.14)	0	0.64	0.94
	Yes	4	−0.18 (−0.51, 0.14)	0	0.28	0.09

¹All studies with control groups that received an intervention were removed. ICC, interclass correlation coefficient; SMD, standardized mean difference.

In 2018, Li et al. (40) published a meta-analysis reporting that nut consumption resulted in a significant reduction in BW, BMI, and WC. This is contrary to our findings, but there are a few possible reasons for this discrepancy. First, since the previous meta-analysis was not focused on substitution instructions, all included studies were analyzed together for each outcome variable while ours were separated out based on the presence or absence of dietary substitution instructions. Second, our inclusion criteria were stricter than the previous meta-analysis. We excluded 30 studies due to controlled-feeding methodology, while the publication by Li et al. included 11 controlled-feeding trials. Likewise, we excluded weight-loss trials, but Li et al. included these trials. Finally, our weighted ESs were also standardized, while theirs was not, and Li et al. (40) did not report on BF%. Together, there are sufficient differences between the types of studies used, and the categorization of studies, in our meta-analysis compared with Li et al. (40) that likely contributed to differences in overall conclusions. This demonstrates the importance of carefully examining study parameters and the overall design and intent of each meta-analysis. Unfortunately, it can make overall interpretations or messages to the general public challenging. Based on their conclusions and ours, we can, with some confidence, state that frequent tree nut consumption does not lead to weight gain in clinical trial studies.

The overall risk of bias, assessed by the Cochrane risk-of-bias tool for RCTs, was “some concern” for 37 of 55 studies. This assessment for RCTs is conservative, and a

rating of “some concern” does not indicate that the study maintained poor quality. Many studies were rated as “some concern” in domain 5 of the assessment tool because a priori statistical analysis plans were not available in the study’s clinical trial registration. Notably, this lack of information does not necessarily mean that the statistical methods were not planned a priori. If a study received a rating of “some concern” in 1 domain, the study’s overall score was automatically also “some concern.” Nine studies were rated as low risk of bias and 9 studies were rated as high risk of bias. Table 6 details the ratings that each study received in each domain of the tool. Visual inspection of funnel plots and most Egger’s tests indicated no publication bias. However, the Egger’s tests for effects with dietary substitution instructions that reported BW and BMI were significant, so results should be interpreted with caution.

This meta-analysis is not free of limitations. For example, within the category of studies that contained dietary substitution instructions, the type of substitution instruction and the degree of contact with research personnel varied across studies. Likewise, a variety of nuts and dosages of nuts were used in the studies included in the meta-analysis, which could have influenced the results. For example, walnuts are rich in PUFAs while pecans are rich in MUFAs (99). The differences in fatty acid profiles between nuts may alter each nut’s potential for promoting weight maintenance, possibly through different effects on appetite (111) and/or metabolism (112). However, despite the variations in substitution instructions, types of nut, and dosage of

TABLE 5 Overview of results from sensitivity analysis in clinical trials involving nut consumption in adults¹

Outcome variable	Substitution instruction?	n	SMD (95% CI)	I ² , %	P	Egger's test
Weight, kg	No	22	0.01 (−0.08, 0.10)	0	0.87	0.63
	Yes	14	−0.03 (−0.15, 0.09)	0	0.65	0.02
BMI, kg/m ²	No	18	0.02 (−0.08, 0.12)	0	0.73	1.00
	Yes	10	−0.01 (−0.17, 0.14)	0	0.87	0.10
Waist circumference, cm	No	14	0.00 (−0.10, 0.10)	0	0.96	0.90
	Yes	7	0.00 (−0.15, 0.15)	0	0.98	0.62
Total body fat, %	No	11	−0.02 (−0.17, 0.13)	0	0.77	0.03
	Yes	5	−0.32 (−0.61, −0.03)	35.4	0.03	0.28

¹All crossover studies were removed. ICC, interclass correlation coefficient; SMD, standardized mean difference.

TABLE 6 Results from the Cochrane risk-of-bias tool for randomized controlled trials assessment for included clinical trials involving nut consumption in adults¹

Study, year (reference)	D1	D2	D3	D4	D5	Overall
Abbaspour et al., 2019 (51)	Low	Low	Low	Low	SC	SC
Agebratt et al., 2016 (52)	Low	Low	Low	Low	SC	SC
Bashan et al., 2018 (53)	SC	Low	Low	Low	SC	SC
Bento et al., 2014 (24)	Low	Low	SC	Low	Low	SC
Bitok et al., 2018 (54)	Low	Low	Low	Low	Low	Low
Burns-Whitmore et al., 2014 (91)	Low	Low	Low	Low	Low	Low
Canudas et al., 2019 (55)	Low	Low	Low	Low	Low	Low
Carughi et al., 2019 (56)	Low	Low	Low	Low	SC	SC
Casas-Agustench et al., 2011 (57)	Low	Low	Low	Low	SC	SC
Chisholm et al., 2005 (58)	Low	Low	Low	Low	Low	Low
Cohen and Johnston, 2011 (59)	Low	Low	Low	Low	SC	SC
Damasceno et al., 2011 (9)	Low	High	Low	Low	Low	High
Damavandi et al., 2019 (61)	Low	Low	Low	Low	SC	SC
Damavandi et al., 2013 (60)	Low	Low	Low	Low	SC	SC
Davidi et al., 2011 (62)	Low	Low	Low	Low	SC	SC
de Souza et al., 2018 (63)	Low	Low	Low	Low	SC	SC
Dhillon et al., 2018 (64)	Low	Low	Low	Low	SC	SC
Fantino et al., 2019 (65)	Low	Low	Low	Low	SC	SC
Gulati et al., 2014 (66)	Low	Low	Low	Low	SC	SC
Hernández-Alonso, et al., 2014 (67)	Low	Low	High	Low	Low	High
Hiraoka-Yamamoto et al., 2004 (68)	Low	Low	Low	Low	SC	SC
Hollis et al., 2007 (32)	Low	Low	SC	Low	Low	SC
Jamshed et al., 2015 (25)	Low	Low	High	Low	Low	SC
Jenkins et al., 2018 (89)	Low	Low	Low	Low	SC	SC
Jenkins et al., 2002 (69)	Low	Low	SC	Low	Low	SC
Jung et al., 2018 (70)	Low	Low	Low	Low	Low	Low
Katz et al., 2012 (96)	Low	Low	Low	Low	Low	Low
Kasliwal et al., 2015 (71)	Low	Low	Low	Low	SC	SC
Lee et al., 2014 (72)	Low	Low	Low	Low	SC	SC
Liu et al., 2017 (73)	Low	Low	High	Low	SC	SC
Ma et al., 2010 (17)	Low	Low	Low	Low	Low	Low
Mercanligil et al., 2007 (74)	Low	High	Low	Low	Low	High
Mohan et al., 2018 (75)	Low	Low	Low	Low	SC	SC
Morgan et al., 2000 (11)	Low	Low	SC	Low	SC	SC
Njike et al., 2017 (76)	Low	Low	Low	Low	SC	SC
Nouran et al., 2010 (77)	Low	Low	SC	Low	Low	SC
O'Byrne et al., 1997 (78)	SC	Low	SC	Low	SC	High
Olmedilla-Alonso et al., 2008 (79)	Low	Low	Low	Low	Low	Low
Palacios et al., 2019 (90)	Low	Low	High	Low	Low	High
Razquin et al., 2010 (92)	SC	High	Low	Low	SC	High
Ros et al., 2004 (80)	Low	High	Low	Low	Low	High
Ruisinger et al., 2015 (81)	Low	Low	Low	Low	SC	SC
Salas-Huetos et al., 2018 (82)	Low	Low	Low	Low	SC	SC
Spiller et al., 1998 (83)	Low	Low	Low	Low	SC	SC
Sweazea et al., 2014 (84)	SC	Low	Low	Low	SC	SC
Tan et al., 2013 (13)	Low	Low	Low	Low	SC	SC
Tapsell et al., 2009 (18)	Low	Low	Low	Low	SC	SC
Tapsell et al., 2004 (85)	Low	Low	Low	Low	SC	SC
Tey et al., 2013 (86)	Low	Low	Low	Low	SC	SC
Tey et al., 2011 (97)	Low	Low	Low	Low	SC	SC
Wu et al., 2010 (87)	Low	Low	Low	Low	SC	SC
Zaveri et al., 2009 (88)	High	Low	High	Low	SC	High
Kocyigit et al., 2006 (93)	Low	Low	Low	Low	SC	SC
Eastman et al., 2005 (94)	High	Low	High	Low	SC	High
Hwang et al., 2019 (95)	Low	Low	Low	Low	Low	Low

¹D1, bias due to randomization; D2, bias due to deviations from intended intervention; D3, bias due to missing data; D4, bias due to outcome measurement; D5, bias due to selection of reported result; SC, some concerns.

nut, the meta-analysis resulted in low heterogeneity between studies.

Another possible limitation is that the inclusion of crossover designs introduces possible unit-of-analysis error

(47). This error due to crossover designs is often considered to be conservative because these studies may be underweighted in the analysis (47). Therefore, this limitation did not outweigh the potential loss of sample size if all

crossover studies were excluded. However, to further confirm that the inclusion of crossover studies in the main analysis did not impact the overall results, we removed all crossover studies in the second sensitivity analysis (Table 5). The results of this sensitivity analysis did not significantly change from the main analysis. Finally, weight and body-composition outcomes were not reported in 34 studies that were entered into the full-text review. Corresponding authors were always contacted when data were missing, but responses were often not received or the data were not collected.

In conclusion, based on the studies included in this meta-analysis, nut consumption does not result in changes in BW, BMI, or WC in studies with or without substitution instructions. Nut consumption may result in decreased BF% when substitution instructions are used. These results suggest that nuts may be consumed, even in large quantities, without changes in BW or body composition.

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