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A systematic review and meta-analysis of nutrition therapy compared with dietary advice in patients with type 2 diabetes

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ABSTRACT

Background: Despite recommendations, many patients with type 2 diabetes receive dietary advice from nurses or doctors instead of individualized nutrition therapy (INT) that is provided by a dietitian.

Objective: We performed a meta-analysis to compare the effect of INT that is provided by a registered dietitian with the effect of dietary advice that is provided by other healthcare professionals.

Design: A systematic review was conducted of Cochrane library databases, EMBASE, CINAHL, and MEDLINE in the period 2004–2017 for guidelines, reviews, and randomized controlled trials (RCTs) that assessed the outcomes glycated hemoglobin (HbA1c), weight, body mass index (BMI; in kg/m^2), and LDL cholesterol. Risk of bias and the quality of evidence were assessed according to the Grading of Recommendations Assessment, Development and Evaluation guidelines.

Results: We identified 5 RCTs comprising 912 participants in total. In the first year of intervention (at 6 or 12 mo), nutrition therapy compared with dietary advice was followed by a 0.45% (95% CI: 0.36%, 0.53%) lower mean difference in HbA1c, a 0.55 (95% CI: 0.02, 1.1) lower BMI, a 2.1-kg (95% CI: 1.2-, 2.9-kg) lower weight, and a 0.17-mmol/L (95% CI: 0.11-, 0.23-mmol/L) lower LDL cholesterol. No longer-term data were available. Some of the included studies had a potential bias, and therefore, the quality of the evidence was low or moderate. In addition, it was necessary to pool primary and secondary outcomes.

Conclusions: INT that is provided by a dietitian compared with dietary advice that is provided by other health professionals leads to a greater effect on HbA1c, weight, and LDL cholesterol. Because of the potential bias, we recommend considering nutrition therapy that is provided by a dietitian as part of lifestyle intervention in type 2 diabetes, but further randomized studies are warranted. *Am J Clin Nutr* doi: https://doi.org/10.3945/ajcn.116.139626.

Keywords: dietary advice, individualized nutrition therapy, meta-analysis, review, type 2 diabetes

INTRODUCTION

Nutrition therapy is an integral part of the treatment of type 2 diabetes, and together with self-management education and physical activity, it has beneficial effects on weight, metabolic control, and general wellbeing. International guidelines have recommended that all individuals with diabetes should receive individualized nutrition therapy (INT), preferably that which is provided by a dietitian with specific expertise and skills in nutrition therapy (1–3).

Despite these recommendations (1), many patients with type 2 diabetes receive dietary advice from nurses or doctors instead of INT that is provided by a dietitian. Before randomization to receive early medication in the UK Prospective Diabetes Study study of newly diagnosed type 2 diabetic subjects, a change in diet that was achieved with INT was associated with a reduction of ≤2 percentage points in glycated hemoglobin (HbA1c) (4). Whether a similar effect can be achieved merely by dietary advice is unclear. Therefore, we have focused on the evidence from randomized controlled trials (RCTs) of INT compared with dietary advice in a setting in which other elements of a lifestyle intervention are comparable.

The aim of this study was to evaluate the effect of nutrition therapy (nutrition assessment, nutrition education and counseling, and monitoring and evaluation) that is provided by a registered dietitian compared with dietary advice that is provided by other healthcare professionals. By searching the literature for high-quality randomized trials and subsequent meta-analyses, we aimed to identify and quantify the possible different effects on selected clinical outcomes.

METHODS

Eligibility criteria

We specified eligibility criteria for the search and meta-analyses using the determination of the population, intervention, comparison, and outcomes approach. We subsequently defined the following specific question to be explored in the literature: Is nutrition therapy superior to dietary advice in patients with type 2 diabetes?

The population comprised subjects with type 2 diabetes on the basis of clinical criteria. The intervention was nutrition therapy compared with dietary advice in RCTs. The selected primary

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Abbreviations used: GRADE, Grading of Recommendations Assessment, Development and Evaluation; HbA1c, glycated hemoglobin; INT, Individualized nutrition therapy; RCT, randomized controlled trial.

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outcomes of the analysis were glycemic control (HbA1c) and BMI (in kg/m^2) after ≥1 y. Secondary outcomes were HbA1c, BMI or weight, and LDL cholesterol before 1 y. Other outcomes were quality of life and dropout rates. Anthropomorphic data were not considered because they were expected to be limited.

Information sources and search strategy

A research librarian performed a systematic literature search of the following databases: EMBASE (www.elsevier.com/solutions/embase-biomedical-research), MEDLINE (www.ncbi.nlm.nih.gov/pubmed), CINAHL (www.ebscohost.com/nursing/products/cinahl-databases/cinahl-complete), and Cochrane Library (www.cochranelibrary.com) databases. Primarily, the literature search was performed in October 2014. The search was limited to references that were published in English or Scandinavian languages from January to October 2014. The following 3 searches were made: *1*) for guidelines, *2*) for reviews, and *3*) for RCTs. The results of all searches were entered into the Covidence software program (2014 version) for analyses (5). In April 2017, we performed a supplementary search for guidelines, reviews, and RCTs that were published from October 2014 to April 2017.

Study selection

After each search, on the basis of titles and abstracts, one author (OS) extracted relevant reports and papers for a full-text evaluation by 2 independent authors (GM, HKA, or OS). Only high-quality guidelines that were based, first, on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines or similar evaluation systems and, second, on systematic reviews of RCTs were included. Clinical guidelines were evaluated with the use of Appraisal of Guidelines for Research and Evaluation II software (AGREE II; Agree Next Steps Consortium, www.agreetrust.org) (6) if they were relevant to the issue we were addressing. Similarly, systematic reviews were evaluated with the use of A Measurement Tool to Assess Systematic Reviews (7).

Evaluations were performed by 2 independent authors (GM, HKA, or OS). Disagreements were primarily resolved through discussions and, second, by the third author.

Data-collection process and risk of bias in individual studies

Two reviewers independently extracted data from the included RCTs and recorded details about study designs, interventions, participants, and outcome measures.

Risk of bias was assessed against the following key criteria: a random-sequence generation; allocation concealment; blinding of participants, personnel, and assessors; incomplete outcome data; selective outcome reporting; and other sources of bias in accordance with the recommendations of the Cochrane Collaboration (8). The following ranking was used: Low risk, high risk, or unclear (either a lack of information or uncertainty over a potential bias). Authors resolved disagreements by consensus and consulted a third author if necessary.

RESULTS

The search revealed 5 guidelines on the basis of GRADE guidelines or other comparable evaluation systems. Three of these guidelines (2, 9, 10) were of sufficient quality according to the Appraisal of Guidelines for Research and Evaluation, but none of them addressed the issues of the present review.

Seven reviews formed the primary search, and 4 reviews from the supplementary search were selected for full-text assessment (**Figure 1**). The predefined criteria for entering the analysis and the issues we addressed were not fulfilled in any of the reviews.

From the primary search for RCTs, 2 studies were included (11, 12), and from the supplementary search, 1 study was included in the analysis (13). In addition, we included 1 older study (14) that fulfilled the criteria and 1 study (15) from the primary search after a mutual reassessment. Both of the studies have been cited in previous and present American guidelines (1, 16).

Study characteristics and risk of bias

All trials were conducted in outpatient settings. Four trials used a parallel RCT design (11, 12, 14, 15), and 1 trial used cluster randomization with each cluster representing a community (13). In total, 912 subjects with type 2 diabetes were included. Only the groups who were randomly assigned to nutrition therapy and dietary advice were included and not the group

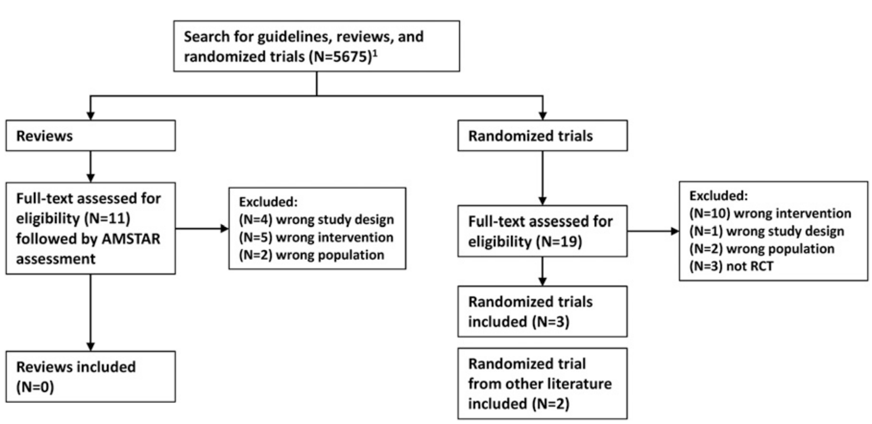

FIGURE 1 Flow diagram of the study search and selection process. Guidelines, reviews, and RCTs were identified from EMBASE, MEDLINE, CINAHL, and Cochrane Library databases and through manual searches of reference lists of selected studies and reviews. [1]The primary search was from 2004 to 2014 for guidelines, reviews (n = 897), and randomized trials (n = 2655). A supplementary search was conducted for reviews and randomized trials from 2014 to 2017 (n = 2123). AMSTAR, A Measurement Tool to Assess Systematic Reviews; RCT, randomized controlled trial.

TABLE 1
Characteristics of randomized controlled trials included in the systematic review[1]

Study, year (ref)	Country	Study design	Setting; duration, mo	Participants	Intervention	Control	Notes	Outcomes	Dropouts, *n*
Andrews et al., 2011 (11)	United Kingdom	RCT, parallel groups	Outpatient; 12	347 subjects with type 2 diabetes; mean age: 60 y; men: 65%	Diet: nutrition therapy (dietitian) at baseline and every 3 mo	Standard dietary advice at baseline, after 6 and 12 mo	3-armed study; nutrition therapy and exercise group excluded (n = 246)	HbA1c (%), blood pressure, lipid profile, weight (kg), body composition, waist and hip circumferences, BMI (in kg/m^2), physical activity, and medication use	8 (6 in control group)
Huang et al., 2010 (12)	Taiwan	RCT, parallel groups	Outpatient; 12	154 subjects with type 2 diabetes; mean age: 57 y; men: 34%	Individualized nutrition therapy (dietitian), instruction on self-monitoring of glucose, medications, exercise, foot care, and complication management	Standard care including a summary of dietary principles by nurses	—	BMI, HbA1c (%), and LDL cholesterol	39 (21 in control group)
Franz et al., 1995 (14)[2]	United States	RCT, parallel groups	Outpatient; 6	179 subjects with type 2 diabetes; mean age: 56 y; men: 45%	One visit with a dietitian at baseline and 2 follow-up visits	One visit with a dietitian at baseline	—	BMI, HbA1c (%), LDL cholesterol, and weight (kg)	44 (after study start)
Coppell et al., 2010 (15)	New Zealand	RCT, parallel groups	Outpatient; 6	104 subjects with type 2 diabetes; mean age: 58 y; men: 41%	2 individual sessions with a dietitian at baseline followed by monthly sessions	Dietary advice at baseline	One subject excluded from intervention group with slow-onset type 1 diabetes	HbA1c (%), weight, BMI, waist circumference, blood pressure, and lipids	11 (4 in control group)
Liu et al., 2015 (13)	China	RCT cluster	Outpatient; 12	128 subjects with type 2 diabetes; mean age: 63 y; men: 39%	3 monthly 6-h sessions with a dietitian	Dietary advice at baseline by clinician	Cluster represented a community	HbA1c (%), weight, BMI, blood pressure, and lipids	11 (5 in control group)

[1] HbA1c, glycated hemoglobin; RCT, randomized controlled trial; ref, reference.
[2] Only data from 179 of 247 enrolled patients were available.

TABLE 2
Summary of findings: nutrition therapy compared with dietary advice[1]

Outcomes	Mean (95% CI) effect in intervention group	Participants (studies), n	Quality of evidence (GRADE)
HbA1c ≤12 mo, %	0.45 (0.53, 0.36) lower	912 (5)	low[2,3]
Weight ≤12 mo, kg	2.06 (2.94, 1.18) lower	611 (3)	moderate[2]
BMI ≤12 mo, kg/m^2	0.55 (1.07, 0.02) lower	762 (4)	low[2,4]
LDL ≤12 mo, mmol/L	0.17 (0.23, 0.11) lower	750 (4)	moderate[2]

[1] Patient or population consisted of patients with type 2 diabetes in an outpatient setting. The intervention was nutrition therapy and was compared with dietary advice. GRADE working group grades of evidence were as follows—high quality: further research is very unlikely to change our confidence in the estimate of effect; moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; and very low quality: we are very uncertain about the estimate. Outcomes are for 6- or 12-mo results. Summary statistics were determined with the use of a random-effects model. GRADE, Grading of Recommendations Assessment, Development and Evaluation; HbA1c, glycated hemoglobin.

[2] Downgraded 1 level for heterogeneity; I^2 = 71%.

[3] Downgraded 1 level for serious risk of bias.

[4] Downgraded 1 level for indirectness.

who was randomly assigned to nutrition therapy and exercise (n = 246) from the study by Andrews et al. (11).

Study characteristics are shown in **Table 1**. The mean age of participants was 57–63 y, and 53% of participants were men. The duration of interventions was 6 mo in 2 trials and 12 mo in 3 trials. Relevant outcomes from the ends of trials were available. BMI before 1 y and HbA1c after 1 y and later were primary outcomes. Therefore, to make a meaningful analysis, we pooled results after 6 or 12 mo in the meta-analysis although they represented a mixture of primary and secondary outcomes.

The number of nutrition-therapy sessions ranged from 3 to 6. The duration of each session was unclear in most of the trials. Nutrition therapy was provided by a dietitian with specific expertise and skills in diabetes and nutrition.

There were no differences in baseline characteristics between groups in the individual studies except in the study by Huang et al. (12) in which patients in the control group had both higher BMI and higher diastolic blood pressure than those of the intervention group at baseline.

Between studies, baseline BMI was much lower in the 2 Asian studies (26–27) (12, 13) than in the studies of non-Asians (33–35). HbA1c was close to normal (6.5%) at baseline in the study by Andrews et al. (11), just <8% in the study by Liu et al. (13), and >8% in the other studies (12, 14, 15).

Risk of bias was assessed from the available information via the Cochrane Risk of Bias tool (8). In all 5 studies, subjects were randomly assigned before the intervention. A random-sequence–generation method was stated in the studies by Andrews et al. (11), Huang et al. (12), and Coppell et al. (15) but not in the studies by Liu et al. (13) and Franz et al. (14). In the Chinese study, 2 communities were randomly assigned to either the intervention or a control (13). This assignment represented high risks of recruitment and selection bias. Allocation concealment was stated in the studies by Andrews et al. (11) and Coppell et al. (15). The blinding of participants and personnel (performance bias) was not possible in the present studies, but this aspect was considered an important component of the overall risk-of-bias assessment. In the study by Andrews et al. (11), the participants were informed about the intervention, which led to high risk of performance bias. The blinding of outcome assessors was reported in 4 studies. Apart from the study by Andrews et al. (11), the method of follow-up was unclear in the control groups. No other potential sources of bias were identified from the studies.

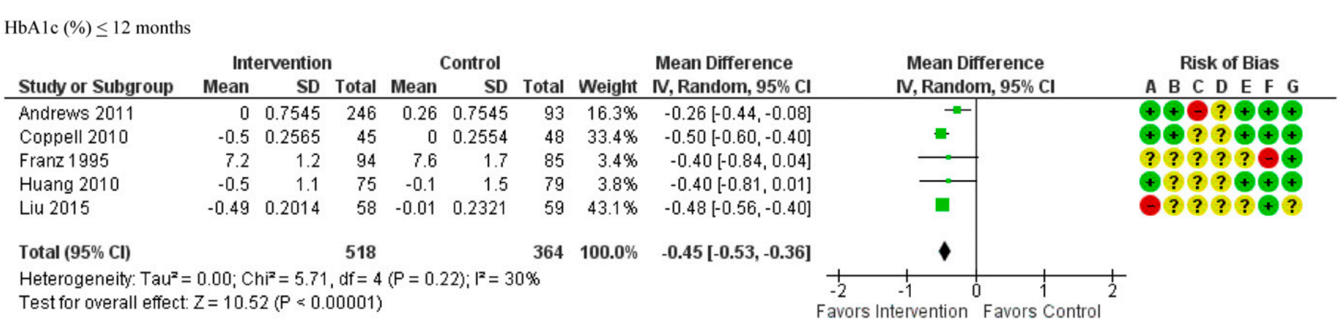

FIGURE 2 Forest plots of HbA1c (expressed as %) during nutrition therapy compared with during the receipt of dietary advice in type 2 diabetes. Green squares indicate the weight of the evidence from each of the studies; the black diamond is the total mean difference, and the width of the diamond indicates the 95% CI. Risk-of-bias categories were as follows: (A) random-sequence generation, (B) allocation concealment, (C) blinding of participants and personnel, (D) blinding of outcome assessment, (E) incomplete outcome data, (F) selective reporting, and (G) other bias; green+: fulfilled, yellow?: data not available, and red-: not fulfilled. References listed are Andrews et al. (11), Coppell et al. (15), Franz et al. (14), Huang et al. (12), and Liu et al. (13). HbA1c, glycated hemoglobin; IV, inverse variance.

Weight (kg) ≤ 12 months

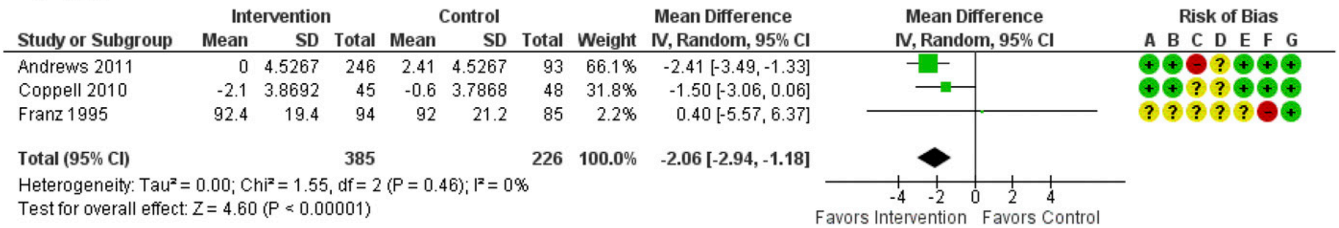

FIGURE 3 Forest plots of weight (expressed as kg) during nutrition therapy compared with during the receipt of dietary advice in type 2 diabetes. Green squares indicate the weight of the evidence from each of the studies; the black diamond is the total mean difference, and the width of the diamond indicates the 95% CI. Risk-of-bias categories were as follows: (A) random-sequence generation, (B) allocation concealment, (C) blinding of participants and personnel, (D) blinding of outcome assessment, (E) incomplete outcome data, (F) selective reporting, and (G) other bias; green+: fulfilled, yellow?: data not available, red-: not fulfilled. References listed are Andrews et al. (11), Coppell et al. (15), and Franz et al. (14). IV, inverse variance.

Overall, risk of bias was assessed as being low in 3 of the included studies (11, 12, 15). In the older study by Franz et al. (14), the paper was unclear for most of the components, and the study by Liu et al. (13) has high risk of bias.

Effects of the intervention

Table 2 shows the summary of finding of the meta-analysis. **Figures 2–5** show Forest plots of the outcomes. Compared with dietary advice, nutrition therapy (INT) was followed by a 0.45-percentage point (95% CI: 0.36-, 0.53-percentage point) lower mean HbA1c (Figure 2) in the first year (at 6 or 12 mo), body weight was 2.1 kg (95% CI: 1.2, 2.9 kg) lower (Figure 3), BMI was 0.55 (95% CI: 0.02, 1.1) lower (Figure 4), and LDL cholesterol was 0.17 mmol/L (95% CI: 0.11, 0.23 mmol/L) lower (Figure 5). No long-term data on HbA1c or body weight were reported, and studies contained no reports on the quality of life.

In the studies by Andrews et al. (11) and Coppell et al. (15), waist circumference at 12 and 6 mo decreased 2.8 and 1.6 cm more, respectively, in the nutrition-therapy groups. The waist-to-hip ratio was unchanged in the study by Franz et al. (14), and the studies by Huang et al. (12) and Liu et al. (13) contained no anthropometric measures.

Dropouts

The reported dropout rate varied considerably from 2.3% (11) to 25.3% (12) but with no difference between groups (Table 1).

DISCUSSION

This meta-analysis was conducted according to the GRADE criteria and shows that INT that was given by certified dietitians compared with dietary advice that was given by nurses and doctors was followed by a greater improvement in glycemic control (HbA1c), a larger loss of weight, and a greater decline in LDL cholesterol. The effects were seen after 6 or 12 mo of intervention. No follow-up or longer-term data were available. To our knowledge, this clinically important effect of nutrition therapy has not been estimated before in meta-analyses of randomized trials.

For HbA1c, the baseline values in the large, high-quality study by Andrews et al. (11) were close to the normal range, which could probably have minimized the overall estimate of the effect of INT (Figure 2). It is clinically well recognized that the magnitude of the effect of an intervention on glycemic control depends on the baseline HbA1c as has been shown in reviews of lifestyle interventions (17, 18). Compared with usual care, the effect of a lifestyle intervention on HbA1c was limited when baseline values was <7.0% (53 mmol/mol). Furthermore, in a review of the effect of nutrition therapy in prediabetes, HbA1c declined ∼0.3 percentage points compared with the effect of usual care (19).

A number of randomized trials have shown a significant effect of a lifestyle intervention on glycemic control (HbA1c), weight and BMI, and quality of life in type 2 diabetes (20). The lifestyle intervention consisted of patient education and nutrition therapy and has been especially efficient when it has been based on a self-management strategy (18) and included exercise (21). However,

BMI (kg/m²) ≤ 12 months

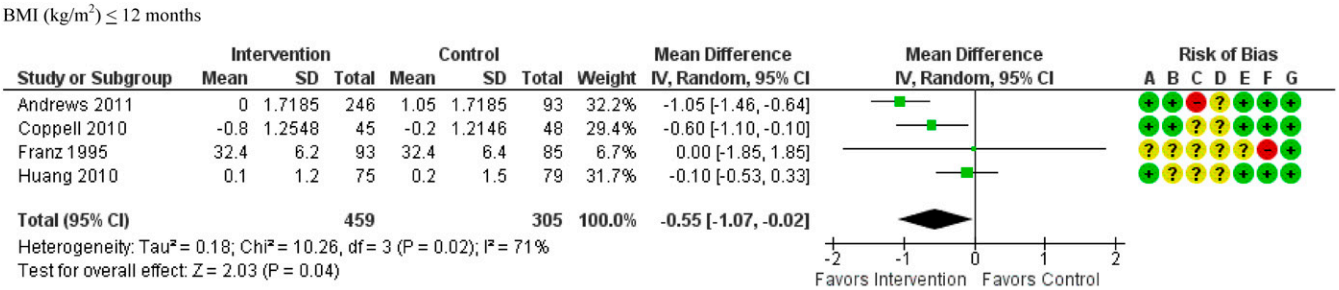

FIGURE 4 Forest plots of BMI (in kg/m²) during nutrition therapy compared with during the receipt of dietary advice in type 2 diabetes. Green squares indicate the weight of the evidence from each of the studies; the black diamond is the total mean difference, and the width of the diamond indicates the 95% CI. Risk-of-bias categories were as follows: (A) random-sequence generation, (B) allocation concealment, (C) blinding of participants and personnel, (D) blinding of outcome assessment, (E) incomplete outcome data, (F) selective reporting, and (G) other bias; green+: fulfilled, yellow?: data not available, red-: not fulfilled. References listed are Andrews et al. (11), Coppell et al. (15), Franz et al. (14), and Huang et al. (12). IV, inverse variance.

LDL-cholesterol ≤ 12 months

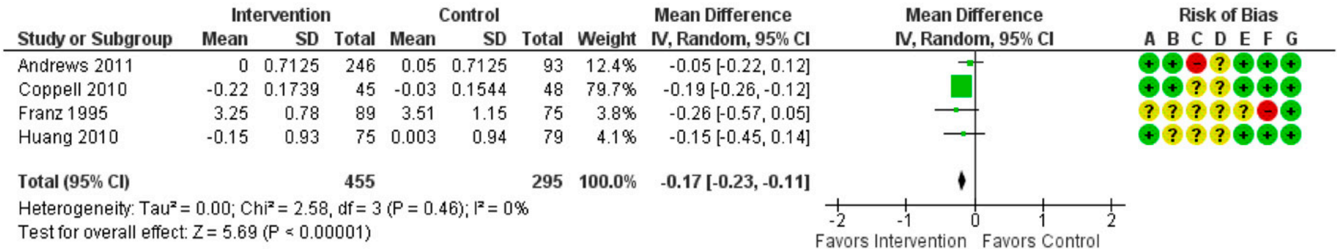

FIGURE 5 Forest plots of LDL-cholesterol concentrations (expressed as mmol/L) during nutrition therapy compared with during the receipt of dietary advice in type 2 diabetes. Green squares indicate the weight of the evidence from each of the studies; the black diamond is the total mean difference, and the width of the diamond indicates the 95% CI. Risk-of-bias categories were as follows: (A) random-sequence generation, (B) allocation concealment, (C) blinding of participants and personnel, (D) blinding of outcome assessment, (E) incomplete outcome data, (F) selective reporting, and (G) other bias; green+: fulfilled, yellow?: data not available, red-: not fulfilled. References listed are Andrews et al. (11), Coppell et al. (15), Franz et al. (14), and Huang et al. (12). IV, inverse variance.

in these studies, the beneficial effect of patient education, nutrition therapy, and exercise could not be discriminated.

The observed effect of INT compared with dietary advice on body weight was of the same magnitude (a reduction of ∼1.5–2 kg) as was shown during short-term, self-management education programs (20) except in the Action for Health in Diabetes study study (21) in which a much greater weight reduction after 1 y was shown. The effect of INT on LDL cholesterol has, in previous studies, been shown to be present only after 1 y of intervention (20, 21).

Limitations

The design of the included studies was comparable, except for the study by Liu et al. (13). A low HbA1c value at baseline in the largest and most important study (11) of the review may have led to an underestimation of the effect of INT. Including short term secondary outcomes and studies with potential selection and performance bias may on the other hand have led to an overestimation of the effect. The review included Asians patients (12, 13), where including changes in anthropometric measures in the analysis probably would have been more informative than using BMI and weight. There were no data on quality of life. No relevant data from beyond 1 y were available, and it is therefore unclear whether nutrition therapy with a limited number of sessions has any long-term effects. The Action for Health in Diabetes study demonstrated the importance of a continuous intervention in the maintenance of lifestyle changes (21).

Conclusion

In conclusion, the present review suggests recommending nutrition therapy to type 2 diabetic patients in a number of sessions lead by a certified dietitian rather than giving dietary advice to adult subjects with type 2 diabetes.

We thank Conni Skrubbeltrang for writing the search protocols and performing the search of the literature for guidelines, reviews, and randomized trials.

The authors' responsibilities were as follows—OS: was the guarantor for conducting the study according to GRADE criteria; HKA: performed the meta-analysis; and all authors: participated in the design and writing of the manuscript and read and approved the final manuscript. OS received a grant from the Danish Health Authority as an author of the Danish National Clinical Guideline for lifestyle intervention in type 2 diabetes. None of the authors reported a conflict of interest related to the study.

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