Legumes

No. 2021/41Ee, The Hague, November 16, 2021

Background document to:
Dutch dietary guidelines for people with type 2 diabetes
No. 2021/41e, The Hague, November 16, 2021

Health Council of the Netherlands

contents

01 introduction

This background document belongs to the advisory report *Dutch dietary guidelines for people with type 2 diabetes*.[1] It describes the methodology for the search, selection and evaluation of the literature regarding the relationship between legumes and health outcomes in people with type 2 diabetes. The current background document furthermore describes the evidence on this topic and the conclusions that have been drawn by the Health Council's Committee on Nutrition.

02 methodology

2.1 Research question

The Committee aimed to answer the following question: what is the relationship (effect or association) of a higher consumption of legumes or soy with health outcomes in people with type 2 diabetes?

The Committee aimed to distinguish between short-term (up to 1 year) and long-term (1 year and longer) effects or associations, where possible.

2.2 Legume recommendations and intake in the Netherlands

The Health Council of the Netherlands included a guideline for legume consumption in the *Dutch dietary guidelines 2015* [2], which is as follows: Eat legumes weekly.

This guideline is based on evidence from randomised controlled trials (RCTs) that showed that higher legume consumption lowers LDL cholesterol. There is no quantitative guideline for legume intake.[2] The council has not previously made specific recommendations regarding the intake of legumes for people with type 2 diabetes.

The Dutch adult population consumes legumes on average once every three weeks and the average daily consumption is 5 grams, according to the Dutch National Food Consumption Survey 2012-2016.[3]

2.3 Definition of legumes

Legumes are the seeds from leguminous plants, including beans, lentils, peas or peanuts. Legumes are generally used in dried form or in boiled form (canned or in a jar). Peanuts and soybeans contain more fat than other legumes and are processed in a different way (e.g., into oils, or, for soy, into specific soy products such as tofu). Also, soybeans are rich in isoflavones, which have a phytoestrogenic effect. Phytoestrogens have previously been suggested to induce preventive effects on cardiovascular disease (CVD).[4]

Due to those differences in characteristics between soybeans and other legumes, the Committee aimed to evaluate soybeans and the remaining legumes separately. Moreover, in the evaluation of the effects or associations of soybeans with health outcomes, the Committee aimed to evaluate only studies that used whole soybeans (thus excluding studies that used isolated substances of soybeans, such as soy protein or isoflavones). Similar to the approach used for the *Dutch dietary guidelines 2015*, peanuts have not been evaluated in this background document since they are often studied together with nuts.

2.4 Outcomes

The Committee selected the following health outcomes for this advisory report (for which a detailed motivation is provided in the background document *Methodology for the evaluation of evidence*[5]):

Surrogate outcomes:

- Glycated haemoglobin (HbA1c);
- Fasting blood glucose;
- Body weight;
- Systolic blood pressure;
- Low-density lipoprotein (LDL) cholesterol;
- Estimated glomerular filtration rate (eGFR).

Long-term health outcomes:

- Morbidity and/or mortality from total cardiovascular diseases (CVD), coronary heart disease (CHD), stroke, heart failure, chronic obstructive pulmonary disease (COPD), total cancer, breast cancer, colorectal cancer, lung cancer, dementia, depression, chronic kidney disease
- All-cause mortality

Other:

- Diabetes remission: HbA1c <48 mmol/mol and no use of diabetes medication for ≥1 year;
- Diabetes reversion: HbA1c <53 mmol/mol and less medication use for ≥1 year.

For cohort studies, the Committee included only studies with long-term health outcomes.

2.5 Selection and evaluation of literature

2.5.1 Selection procedure

A detailed description of the approach used by the Committee for selecting and evaluating scientific literature is given in the background document *Methodology for the evaluation of evidence*.[5] To summarise, the Committee aimed to base its evaluation of scientific literature on systematic reviews (SRs) and meta-analyses (MAs) of randomised controlled trials (RCTs) and prospective cohort studies examining the effects or associations of higher consumption of soy or legumes with the above-mentioned health outcomes in people with type 2 diabetes.
The literature search for SRs and MAs was performed in PubMed and Scopus in July 2020. The Committee complemented the evidence from SRs and MAs with evidence from recent individual RCTs that were not included in the SRs and MAs. This search was limited to the outcomes already covered in the SRs or MAs. The search strategy, flow diagram of the literature search and detailed description of the selection of articles are provided in **Annex A**.

The Committee only found SRs and MAs of RCTs. In case SRs (without MA) were used for the evaluation, effect estimates from each relevant individual RCT included in the SR were separately described by the Committee. In case MAs were used for the evaluation, the pooled effect estimate of RCTs included in the MA was described.

No SRs or MAs of prospective cohort studies were found. Therefore, the Committee additionally searched for literature references of prospective cohort studies addressing the associations of soy or legume consumption with long-term health outcomes among people with type 2 diabetes in existing dietary guidelines for type 2 diabetes.

2.5.2 Selected articles

For the evaluation of literature regarding soy, no relevant SRs or MAs were found. Two MAs that were found primarily focused on RCTs into isolated substances from soybeans but those were outside the inclusion criteria of the Committee.[6,7]

For the evaluation of literature regarding legumes, one SR of RCTs, performed by Bielefeld et al. (2020)[8], and two recent individual RCTs (by Liu et al. 2018[9] and Ward et al. 2020[10]) were included. All RCTs reported on short-term surrogate outcomes, i.e. HbA1c, fasting blood glucose, body weight, systolic blood pressure and LDL cholesterol. Furthermore, one pooled analysis of prospective cohort studies (Nöthlings et al. 2008[11]) and one individual prospective cohort study (Papandreou et al.2019[12]) on the associations of legume consumption with (cause-specific) mortality were found. No literature turned out to be available within the inclusion criteria of the Committee regarding the surrogate outcome eGFR, the long-term health outcomes COPD, dementia, depression and chronic kidney disease, and diabetes remission and reversion. Therefore, literature regarding those outcomes is not evaluated in the current background document. A more extensive description of the selection of literature is presented in **Annex A**.

2.5.3 Risk of bias

The SR of Bielefeld et al.[8] used the revised *Cochrane Collaboration's tool* (2019) for assessing risk of bias in the included RCTs.[13] The following five domains were evaluated: bias arising from the randomization process, bias due to deviations from the intended interventions, bias due to missing outcome data, bias in measurement of the outcome, bias in selection of the reported result. The risk of bias of the recently published complementary RCTs was assessed by the Committee, using the same *Cochrane Collaboration's tool* (2019).[13]

2.5.4 Drawing conclusions

A detailed description of the approach used to draw conclusions is provided in the background document *Methodology for the evaluation of evidence*.[5] In short, the Committee drew conclusions on (the certainty of) the evidence regarding the effects or associations of higher intake of legumes with health outcomes in people with type 2 diabetes, based on the number of studies, number of participants and number of cases that contributed to the evaluation. It also took into account the risk of bias and heterogeneity between studies. The Committee used the decision tree (**Annex B**) as a tool to support consistency in drawing conclusions.

03
effects and associations of higher legume intake

Below, the scientific evidence for the relationships (effects and associations) of higher legume intake with health outcomes in people with type 2 diabetes is described.

3.1 Evidence from RCTs

3.1.1 HbA1c

The results and characteristics of the RCTs selected in the SR of Bielefeld et al.[8] that provide evidence regarding the effects of an increased legume intake on HbA1c in people with type 2 diabetes are summarised in Table 1. The results and characteristics of recently published individual RCTs that are complementary to the SR are summarised in Table 2. All RCTs reported short-term effects (up to 12 weeks).

Table 1 Summary of the effects of an increased intake of legumes on HbA1c in people with type 2 diabetes: RCTs from the SR of Bielefeld et al.[8]

RCT; Study duration	Jenkins, 2012[14]; 12 weeks	Hassanzadeh-Rostami, 2019[15]; 8 weeks	Simpson, 1981[16]; 6 weeks
Number of participants in intervention (i) and control (c) group	i: 60 c: 61	i: 20 c: 23	i: 18 c: 18
Study design	Parallel RCT	Parallel RCT	Crossover RCT; no washout
Diet of intervention (i) and control (c) group.	i: 190 g/day cooked legumes c: High wheat fibre diet Isocaloric	i: Non-soy legumes 77 g/day c: Red meat Isocaloric	i: Mixed beans 290 g/day c: Low carbohydrate diet Isocaloric
Between-group mean difference	-0.2% (95%CI -0.3, -0.1)	0.1%; *p-value* 0.57	NR; *Mean HbA1c at end of follow-up: i: 8.60%; c: 9.60%; p-value for difference between groups <0.02*
Study population	People diagnosed with type 2 diabetes; BMI[a]: 31 (i) and 30 (c) kg/m^2; men and women; diabetes duration[a]: 9 years; diabetes medications[b]: oral agents; Canada	People diagnosed with type 2 diabetes; BMI[a]: 27 (i) and 26 (c) kg/m^2; men and women; diabetes duration[a]: 8 (i) and 11 (c) years; diabetes medications[b]: oral agents; Iran	People diagnosed with type 2 diabetes; BMI: NR; men and women; diabetes duration: NR; diabetes medications[b]: oral agents, insulin; United Kingdom

BMI: body mass index; c: control group; i: intervention group; NR: not reported; SR: systematic review.

[a] BMI and diabetes duration values represent the average in the study population.
[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

Table 2 Summary of the effects of an increased intake of legumes on HbA1c in people with type 2 diabetes: individual recent RCT.

RCT; Study duration	Liu, 2018[9]; 4 weeks
Number of participants in intervention (i) and control (c) group	i: 51 c: 55
Study design	Parallel RCT
Diet of intervention (i) and control (c) group	i: 48 g extruded adzuki bean/day in convenient food + diabetes diet c: Low-glycaemic index diabetes diet No statistically significant difference in energy intake between i and c
Between-group mean difference	-0.17%; *p-value* 0.55
Study population	People diagnosed with type 2 diabetes; mostly overweight; men and women; diabetes duration[a]: 8 (i) and 9 (c) years; diabetes medications[b]: oral agents and insulin; China

c: control group; i: intervention group; RCT: randomized controlled trial.

[a] Diabetes duration values represent the average in the study population.

[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

The Committee concluded the following:

Intervention studies show that consumption of legumes, compared to control foods without legumes, as part of diets with similar prescribed energy intakes, reduces HbA1c within 4 to 12 weeks in people diagnosed with type 2 diabetes. The evidence is limited.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are 4 RCTs with more than 90 participants included in the evaluation, which excludes a conclusion with strong evidence (for which at least 5 RCTs with more than 150 participants are needed).
2. There is moderate heterogeneity in direction of effects between RCTs. Nevertheless, the Committee concludes there is a reducing effect based on the largest study, with longest duration and with a low risk of bias (Jenkins et al.[14]). That study showed a greater reduction in HbA1c with legume intake than with control foods. This was supported by a smaller RCT, yet at high risk of bias. Moreover, another RCT found an effect in similar direction, though not statistically significant, which may be due to the short study duration and/or due to the use of processed instead of whole legumes. One RCT did not find a reducing effect. However, this may be due to an imbalance in HbA1c between the two study groups at baseline, rather than due to differences in the diets.
3. There is moderate heterogeneity in the size of the effects of the three RCTs reporting (a tendency towards) reducing effects. The Committee noted there were differences in type and dosages of the intervention and control diets, and in study durations, which may have contributed to differences in size of the effects between studies.

Explanation:

Study characteristics and main effects

The Committee did not find any MAs of RCTs on the effect of an increased intake of legumes on HbA1c in people with type 2 diabetes but one SR was found. In the SR of Bielefeld et al.[8]**,** three RCTs were included that addressed effects on HbA1c. In addition, one recently published RCT was found, of Liu et al.[9], making a total of 4 RCTs.

The RCT of Jenkins et al.[14] compared consumption of 190 g/day cooked legumes (intervention group) with a high wheat fibre diet (control group). The aim of the study was to use legumes to lower the glycaemic index of the diet in the intervention group. Other than the legumes, there were no other changes made to the diets that lowered the glycaemic index, therefore the Committee deemed this RCT relevant for the evaluation of the effects of legume consumption. After 12 weeks, a statistically significant greater reduction of 0.2% in HbA1c was found in the intervention group compared to the control group. This study was the largest in terms of number of participants included and had the longest duration.

The RCT of Hassanzadeh-Rostami et al.[15] compared consumption of 2 servings of non-soy legumes for 3 days a week (intervention group) with 2 servings of red meat for 3 days a week (control group). Both groups received a weight-maintenance diet. There was no statistically significant difference between the two groups in the change of HbA1c after eight weeks of follow-up. However, it should be noted there was an imbalance in HbA1c at baseline, with statistically significantly higher HbA1c in the control group (median: 9.5%) than the intervention group (median: 7.7%). As a consequence, there may have been more room for improvement of HbA1c values in the control group than in the intervention group. This may have contributed to the lack of difference in effect between the intervention and control group.

The RCT of Simpson et al.[16] compared a high carbohydrate diet containing leguminous fibre (intervention group) with a standard low carbohydrate diet (control group), both for 6 weeks. More specifically, the intervention group received a diet high in beans (type unspecified). Simpson et al. did not report the HbA1c at baseline and the change in HbA1c during follow-up is therefore unknown. However, there was a statistically significant between-group difference of HbA1c measured at the end of follow-up in favour of the diet high in beans (8.6% in intervention vs. 9.6% in control group; p-value <0.02).

The RCT of Liu et al.[9] compared consumption of a diet with extruded adzuki bean convenient foods (intervention group) to a traditional diabetic low glycaemic index diet (control group) for four weeks. Processed beans were used for the intervention foods, which is different from the above described RCTs that used whole beans. The foods with extruded adzuki beans were provided to the participants. It is not mentioned whether the study diets were isocaloric. Energy intakes of the intervention and control groups were very similar during the intervention period. No difference was found between the intervention and control groups in the reduction of HbA1c after 4 weeks of follow-up. The short intervention period of four weeks may have contributed to the lack of difference in effect since it takes two to three months to observe the full effect on HbA1c. Also, the authors noted that the intervention and control diets may have had a comparable glycaemic index, which is expected to be one of the mechanisms by which legumes could improve glycaemic control. Finally, the Committee notes it is unsure whether the effects of extruded beans can be compared to those of whole beans.

Risk of bias

Bielefeld et al.[8] scored the RCT of Jenkins et al.[14] as low risk of bias and the RCT of Hassanzadeh-Rostami et al.[15] as 'some concerns'. As stated above, in the RCT of Hassanzadeh-Rostami et al., there was a significant difference in baseline HbA1c between the intervention and control groups, which may have biased the study findings. The RCT of Simpson et al.[16] was scored high risk of bias, particularly because of deviation from the intended intervention. Also, there were some concerns regarding the randomization process, measurement of the outcomes and selection of the reported results. The reasoning behind those judgements is not further explained by Bielefield et al. The lack of a wash-out period between the intervention and control diets (cross-over design) may have contributed to the biased results.

The individual RCT of Liu et al.[9] was scored low risk of bias.

Overall quality of the evidence

Bielefeld et al.[8] scored the overall quality of the evidence (the three RCTs listed in Table 1) using GRADE as very low, caused by indirectness (variations between studies in composition of intervention and control diets), imprecision (insufficient sample size) and publication bias (grey literature sources were not included in the search).

Funding

The funding sources of the evaluated studies and conflicts of interests of the authors are presented in **Annex C**. Jenkins et al.[14] reported funding by the Saskatchewan Pulse Growers. The involvement of the funder was not reported and therefore the impact on the study findings remains unclear. For the other studies, no notable funding sources were reported.

Retention rates and compliance

Where reported, retention rates were around 90% and the participants were compliant with the dietary intervention, suggesting those factors likely did not majorly impact the study findings.

Summary

Four RCTs evaluated the differences in effects of diets high in legumes compared to control diets on changes in HbA1c. Two of the RCTs, including the largest RCT with the longest duration and a low risk of bias, showed that HbA1c values reduced statistically significantly more with the diets high in legumes. The other two RCTs showed no statistically significant effects on HbA1c. Of those two, one showed a non-significant increasing effect and one a non-significant decreasing effect. The non-significant increasing effect in one of the RCTs may be due to an imbalance in HbA1c at baseline, rather than due to differences in the diets. Overall, there were differences in type and dosages of the intervention and control diets and in study durations, which may have contributed to differences in results between studies. Where reported, the compliance was overall good and likely did not affect the results.

3.2.1 Fasting blood glucose

The results and characteristics of the RCTs selected in the SR of Bielefeld et al.[8] that provide evidence regarding the effects of an increased legume intake on fasting blood glucose in people with type 2 diabetes are summarised in Table 3. The results and characteristics of recently published individual RCTs that are complementary to the SR are summarised in Table 4. All RCTs reported short-term effects (up to 12 weeks).

Table 3 Summary of the effects of an increased intake of legumes on fasting blood glucose in people with type 2 diabetes: RCTs from the SR of Bielefeld et al.[8]

RCT; **Study duration**	**Jenkins, 2012[14];** **12 weeks**	**Hassanzadeh-Rostami, 2019[15];** **8 weeks**	**Shams, 2010[17];** **6 weeks**	**Hosseinpour-Niazi, 2015[18];** **8 weeks**
Number of participants in intervention (i) and control (c) group	i: 60 c: 61	i: 20 c: 23	i: 30 c: 30	i: 31 c: 31
Study design	Parallel RCT	Parallel RCT	Crossover RCT; washout 3 weeks	Crossover RCT; washout 4 weeks
Diet of intervention (i) and control (c) group	i: 190 g/day cooked legumes c: High wheat fibre diet Isocaloric	i: Non-soy legumes 77 g/day c:Red meat Isocaloric	i:Cooked lentils 50 g/day c:Legume-free diet Isocaloric	i: Cooked mixed legumes 3 cups/ week c: Red meat 2 servings for 3 times a week Isocaloric
Between-group mean difference	-0.11 mmol/L; *p-value* 0.001	-0.08 mmol/L; *p-value* 0.81	-0.05 mmol/L; 95%CI or *p-value* NR	-0.51 mmol/L; *p-value* <0.001
Study population	People diagnosed with type 2 diabetes; BMI[a]: 31 (i) and 30 (c) kg/m^2; men and women; diabetes duration[a]: 9 years; diabetes medications[b]: oral agents; Canada.	People diagnosed with type 2 diabetes; BMI[a]: 27 (i) and 26 (c) kg/m^2; men and women; diabetes duration[a]: 8 (i) and 11 (c) years; diabetes medications[b]: oral agents; Iran.	People diagnosed with type 2 diabetes; BMI[a]: 29 kg/m^2; sex: NR; diabetes duration: NR; diabetes medications[b]: not reported, insulin users excluded; Iran.	People with type 2 diabetes; overweight; men and women; diabetes duration: NR; diabetes medications[b]: not reported, insulin users excluded; Iran.

BMI: body mass index; c: control group; i: intervention group; NR: not reported; RCT: randomized controlled trial.

[a] BMI and diabetes duration values represent the average in the study population.
[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

Table 4 Summary of the effects of an increased intake of legumes on fasting blood glucose in type 2 diabetes: individual recent RCTs.

RCT; Study duration	Liu, 2018[9]; 4 weeks	Ward, 2020[10]; 8 weeks
Number of participants in intervention (i) and control (c) group	i: 51 c: 55	i: 17 c: 17
Study design	Parallel RCT	Crossover RCT; 8 weeks washout
Diet of intervention (i) and control (c) group	i: 48 g extruded adzuki bean/day in convenient food + diabetes diet. c: Low glycaemic index diabetes diet. No statistically significant difference in energy intake between i and c	i: Lupin flour-enriched foods (~45 g/d lupin flour) c: Placebo: same foods without lupin flour No statistically significant difference in energy intake between i and c
Between-group mean difference	0.01 mmol/L; *p-value* 0.97	−0.14 mmol/L; *p-value* 0.79
Study population	People diagnosed with type 2 diabetes; mostly overweight; men and women; diabetes duration[a]: 8 (i) and 9 (c) years; diabetes medications[b]: oral agents and insulin; China.	People diagnosed with type 2 diabetes; BMI[a]: 29 kg/m^2; men and women; diabetes duration[a]: 5 years; diabetes medications[b]: oral agents; Australia.

c: control group; i: intervention group; RCT: randomized controlled trial.

[a] BMI and diabetes duration values represent the averages in the study population.

[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

The Committee concluded the following:

Intervention studies show that consumption of legumes, compared to control foods without legumes, as part of diets with similar prescribed energy intakes, reduces fasting blood glucose within 4 to 12 weeks in people diagnosed with type 2 diabetes. The evidence is limited.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are 6 RCTs, with more than 150 participants included in the evaluation, which is the first step required to mark the evidence as strong. However, there were other considerations that lead to the conclusion of limited evidence, as described below.
2. There is moderate heterogeneity in directions of effects between RCTs. Nevertheless, the Committee concludes there is a reducing effect based on the largest study, with longest duration and with a low risk of bias (Jenkins et al.[14]). That study showed a greater reduction in fasting blood glucose with legume intake than with control foods. This was supported by a smaller RCT, also at low risk of bias. Three RCTs reported no statistically significant differences in effects, though the directions of the effects also pointed towards a reducing effect on fasting blood glucose with the diets high in legumes. The smaller sample sizes, shorter durations and/or use of processed legumes of those three RCTs may have contributed to the lack of statistically

significant reductions. Also, an imbalance in fasting blood glucose between the two study groups at baseline in one of the RCTs may have contributed to the lack of statistically significant reduction. One RCT did not find a reducing effect. However, this may be due to the short intervention period and/or due to the use of processed instead of whole legumes.

3. There is moderate heterogeneity in the size of the effects of the five RCTs reporting (a tendency towards) reducing effects. The Committee noted there were differences in type and dosages of the intervention and control diets and in study durations, which may have contributed to differences in sizes of the effects between studies.

Explanation:

Study characteristics and main effects

The Committee did not find any MAs of RCTs on the effect of an increased intake of legumes on the fasting blood glucose in people with type 2 diabetes, but one SR was found. In the SR of Bielefeld et al.[8], four RCTs were included that addressed effects on fasting blood glucose. In addition, two recently published RCTs were found, of Liu et al.[9] and Ward et al.[10], making a total of 6 RCTs.

The RCTs of Jenkins et al.[14] and Hassanzadeh-Rostami et al.[15] were already described in the evaluation of effects on HbA1c (Section 3.1.1). Jenkins et al. found a statistically significant 0.11 mmol/L greater reduction in fasting blood glucose in the intervention group (cooked legumes diet) compared to the control group (wheat fibre diet). Hassanzadeh-Rostami et al. reported a non-significant greater reduction of 0.08 mmol/L in fasting plasma glucose in the intervention (non-soy legumes) group compared to the control (red meat) group. However, there was an imbalance in glucose values at baseline, with higher glucose in the control group (median: 9.6 mmol/L) than the intervention group (median: 8.0 mmol/L). As a consequence, there may have been more room for improvement of glucose values in the control group than in the intervention group. This may have contributed to the lack of statistical difference in effect between the intervention and control groups.

The RCT of Shams et al.[17] compared cooked lentils (intervention group) with a legume-free diet (control group), each for 6 weeks. At the end of follow-up, a 0.05 mmol/L greater reduction in fasting blood glucose was found in the intervention compared to the control group. However, it is unclear whether this difference between groups is statistically significant. The magnitude of effect is small compared to the other RCTS. This may, among other reasons, be due to the relatively short duration of the RCT.

The RCT of Hosseinpour-Niazi et al.[18] isocalorically compared cooked mixed legumes (intervention group) with red meat (control group), each for 8 weeks. Both the intervention and the control group also followed a Therapeutic Lifestyle diet, which is a diet that focuses on reducing saturated fat and cholesterol intake, weight reduction, and promoting physical activity. A statistically significant 0.51 mmol/L greater reduction in fasting blood glucose was found in the intervention group compared to the control group.

The RCT of Liu et al.[9] was already described in the evaluation of effects on HbA1c (Section 3.1.1) and found no difference in effect on fasting blood glucose in the intervention group (extruded adzuki bean convenient foods) compared to control (traditional diabetic low glycaemic index diet) group. As previously described, the short intervention period of four weeks may have contributed to the lack of difference in effect. Also, the authors noted that the intervention and control diets may have had a comparable glycaemic index, which is expected to be one of the mechanisms by which legumes could improve glycaemic control.

The RCT of Ward et al.[10] compared the effects of consumption of lupin flour-enriched foods (~45 g/d lupin flour; intervention group) to consumption of similar foods that were not enriched with lupin flour (control group), each for eight weeks. Energy intakes were approximately 500 kJ per day lower with the intervention diet compared to the control diet. However, this difference was not statistically significant. Ward et al. found a non-significant 0.14 mmol/L greater reduction of glucose in the intervention group compared to the control group. The small size of the trial in terms of number of participants included may have contributed to the lack of statistical difference in effect. The RCTs of Ward et al. and Liu et al.[9] used processed legumes, in contrast to whole legumes that were used in the RCTs selected for the SR of Bielefeld et al.[8] This may also have contributed to the differences in findings between RCTs.

Risk of bias

Bielefeld et al.[8] scored the RCTs of Jenkins et al.[14] and Hosseinpour-Niazi et al.[18] as low risk of bias and the RCT of Hassanzadeh-Rostami et al.[15] as 'some concerns'. As stated above, in the RCT of Hassanzadeh-Rostami et al., there was a significant difference in baseline glucose between the intervention and control group, which may have biased the study findings. The RCT of Shams et al.[17] was also scored as 'some concerns'. There were some concerns regarding the randomization process, deviation from the intended intervention and selection of the reported results. The reasoning behind those judgements is not further explained by Bielefield et al.

The recent RCTs of Liu et al.[9] and Ward et al.[10] were both scored as low risk of bias.

Overall quality of the evidence

Bielefeld et al.[8] scored the overall quality of the evidence (the four RCTs listed in Table 5) using GRADE as very low, caused by indirectness (variations between studies in composition of intervention and control diets), imprecision (insufficient sample size) and publication bias (grey literature sources were not included in the search).

Funding
The funding sources of the evaluated studies and conflicts of interests of the authors are presented in **Annex C**. Jenkins et al.[14] reported funding by the Saskatchewan Pulse Growers. The involvement of the funder was not reported and therefore the impact on the study findings remains unclear. For the other studies, no notable funding sources were reported.

Retention rates and compliance
Where reported, retention rates varied from around 80 to 90%. Also, where reported, the participants were compliant with the dietary interventions, suggesting this likely did not impact the study findings.

Summary
Six RCTs evaluated the differences in effects of diets high in legumes compared to control diets on changes in fasting blood glucose. Two RCTs, including the largest RCT with the longest duration, reported a statistically significant greater reduction in fasting blood glucose with legume intake than with control foods. Both were judged as low risk of bias. Three RCTs reported no statistically significant differences in effects, though the directions of the effects also pointed towards a reducing effect on fasting blood glucose with the diets high in legumes. Another RCT showed no difference in effect of the legume diet compared to control diet on glucose. However, this may be due to an imbalance in glucose at baseline, rather than due to differences in the diets. There were differences in type and dosages of the intervention and control diets and in study durations, which may have contributed to differences in results between studies. Where reported, the compliance was overall good and likely did not affect the results.

3.1.3 Body weight
The results and characteristics of the RCTs selected in the SR of Bielefeld et al.[8] and providing evidence regarding the effects of an increased legume intake on body weight in people with type 2 diabetes are summarised in Table 5. The results and characteristics of recently published individual RCTs that are complementary to the SR are summarised in Table 6. All RCTs reported short-term effects (up to 12 weeks).

Table 5 Summary of the effects of an increased intake of legumes on body weight in people with type 2 diabetes: RCTs from the SR of Bielefeld et al.[8]

RCT; Study duration	Jenkins, 2012[14]; 12 weeks	Hosseinpour-Niazi, 2015[18]; 8 weeks
Number of participants in intervention (i) and control (c) group	i: 60 c: 61	i: 31 c: 31
Study design	Parallel RCT	Crossover RCT; washout 4 weeks
Diet of intervention (i) and control (c) group	i: 190 g/day cooked legumes c: High wheat fibre diet Isocaloric	i: Cooked mixed legumes 3 cups/ week c: Red meat 2 servings for 3 times a week Isocaloric
Between-group mean difference	-0.7 kg; *p-value* 0.002	BMI reported instead of body weight: -0.10 kg/m^2; *p-value 0.18*
Study population	People diagnosed with type 2 diabetes; BMI[a]: 31 (i) and 30 (c) kg/m^2; men and women; diabetes duration[a]: 9 years; diabetes medications[b]: oral agents; Canada.	People with type 2 diabetes; overweight; men and women; diabetes duration[a]: NR; diabetes medications[b]: not reported, insulin users excluded; Iran.

BMI: body mass index; c: control group; i: intervention group; NR: not reported; RCT: randomised controlled trial; SR: systematic review.

[a] BMI and diabetes duration values represent the average in the study population.
[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

Table 6 Summary of the effects of an increased intake of legumes on body weight in people with type 2 diabetes: individual recent RCTs.

RCT; Study duration	Liu, 2018[9]; 4 weeks	Ward, 2020[10]; 8 weeks
Number of participants in intervention (i) and control (c) group	i: 51 c: 55	i: 17 c: 17
Study design	Parallel RCT	Crossover RCT; 8 weeks washout
Diet of intervention (i) and control (c) group	i: 48 g extruded adzuki bean/day in convenient food + diabetes diet c: Low glycaemic index diabetes diet. No statistically significant difference in energy intake between i and c	i: Lupin flour-enriched foods (~45 g/d lupin flour) c: Placebo: same foods without lupin flour No statistically significant difference in energy intake between i and c
Between-group mean difference	0.07 kg; *p-value* 0.91	-0.17 kg; *p-value* 0.57
Study population	People diagnosed with type 2 diabetes; mostly overweight; men and women; diabetes duration[a]: 8 (i) and 9 (c) years; diabetes medications[b]: oral agents and insulin; China.	People diagnosed with type 2 diabetes; BMI[a]: 29 kg/m^2; men and women; diabetes duration[a]: 5 years; diabetes medications[b]: oral agents; Australia.

BMI: body mass index; c: control group; i: intervention group; NR: not reported; RCT: randomised controlled trial.

[a] BMI and diabetes duration values represent the average in the study population.
[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

The Committee concluded the following:

Intervention studies show that consumption of legumes, compared to control foods without legumes, as part of diets with similar prescribed energy intakes, reduces body weight within 4 to 12 weeks in people diagnosed with type 2 diabetes. The evidence is limited.
The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are 4 RCTs with more than 90 participants included in the evaluation, which excludes a conclusion with strong evidence (for which at least 5 RCTs, with more than 150 participants, are needed).
2. There is moderate heterogeneity in directions of effects between RCTs. Nevertheless, the Committee concludes there is a reducing effect based on the largest study, with longest duration and with a low risk of bias (Jenkins et al.[14]). That study showed a greater reduction in body weight with legume intake than with control foods. Two other RCTs reported no statistically significant differences in effects, though the directions of the effects also pointed towards a reducing effect on body weight with the diets high in legumes. The smaller sample sizes, shorter durations and/or use of processed legumes of those two RCTs may have contributed to the lack of statistically significant reductions. One RCT did not find a reducing effect. However, this may be due the short intervention period and/or due to the use of processed instead of whole legumes.
3. There is moderate heterogeneity in the size of the effects of the two RCTs reporting (a tendency towards) reducing effects on body weight and another RCT reported effects on body mass index (BMI), limiting comparability of the effect sizes. The Committee noted there were differences in type and dosages of the intervention and control diets and in study durations, which may have contributed to differences in sizes of the effects between studies.

Explanation:

Study characteristics and main effects

The Committee did not find any MAs of RCTs on the effect of an increased intake of legumes on body weight in people with type 2 diabetes but one SR was found. In the SR of Bielefeld et al.[8], one RCT was included that addressed effects on body weight and one on BMI.
In addition, two recently published RCTs were found, of Liu et al.[9] and Ward et al.[10], making a total of 4 RCTs.

All four RCTs were already described in the evaluations of HbA1c and/or fasting blood glucose (Sections 3.1.1 and 3.1.2). Jenkins et al.[14] found a statistically significant 0.7 kg greater reduction in body weight in the intervention group (cooked legumes diet) compared to the control group (wheat fibre diet). Hosseinpour-Niazi et al.[18] did not report effects on body weight but instead reported effects on BMI. A non-significant greater reduction of 0.10 kg/m^2 in BMI in the intervention (cooked mixed legumes) compared to the control (red meat) group was found. The Committee notes it is unclear whether body height was measured before and after the intervention to calculate the pre- and post-intervention BMI, or only before the intervention and then used to calculate BMI at both time points. In case the body height was measured at both time points, this may have induced additional measurement error, which could have attenuated the study effects. Ward et al.[10] also reported a greater reduction in body weight in the intervention (lupin flour-enriched foods) compared to the control (similar foods not enriched with lupin flour) group. However, this difference was not statistically significant. The small size of the trial in terms of number of participants included may have contributed to the lack of statistical difference in effect.

Liu et al.[9] found no difference in effect on body weight in the intervention group (extruded adzuki bean convenient foods) compared to control (traditional diabetic low glycaemic index diet) group. The short intervention period of four weeks may have contributed to the lack of difference in effect.

The Committee notes that the prescribed diets of two RCTs were isocaloric[14,18] and, in the other two RCTs[9,10], energy intakes were rather comparable between the intervention and control groups. This may have contributed to the lack of statistically significant effects on body weight in some of the RCTs.

Risk of bias

Bielefeld et al.[8] scored the RCTs of Jenkins et al.[14] and Hosseinpour-Niazi et al.[18] as low risk of bias. The recent RCTs of Ward et al.[10] and Liu et al.[9] were also judged as low risk of bias.

Overall quality of the evidence

Bielefeld et al.[8] did not address the overall quality of the evidence for body weight.

Funding

The funding sources of the evaluated studies and conflicts of interests of the authors are presented in **Annex C**. Jenkins et al.[14] reported funding by the Saskatchewan Pulse Growers. The involvement of the funder was not reported and therefore the impact on the study findings remains unclear. For the other studies, no notable funding sources were reported.

Retention rates and compliance

Where reported, retention rates varied from approximately 80 to 90%. In addition, where reported, the participants were compliant with the dietary intervention, suggesting this likely did not impact the study findings.

Summary

Four RCTs evaluated the differences in effects of diets high in legumes compared to control diets on changes in body weight or BMI. One RCT reported a statistically significant greater reduction in body weight with legume intake than with control foods. Two other RCTs reported no statistically significant differences in effects, though the directions of the effects also pointed towards a reducing effect on body weight with the diets high in legumes. Another RCT showed no difference in effect of the legume diet compared to control diet on body weight. This may be due to the short duration of the RCTs. All RCTs were scored low risk of bias. There were differences in type and dosages of the intervention and control diets and in study durations, which may have contributed to differences in results between studies. Where reported, the compliance was overall good and likely did not affect the results.

3.1.4 Systolic blood pressure

The results and characteristics of the RCTs selected in the SR of Bielefeld et al.[8] and providing evidence regarding the effects of an increased legume intake on systolic blood pressure in people with type 2 diabetes are summarised in Table 7. The results and characteristics of recently published individual RCTs that are complementary to the SR are summarised in Table 8. All RCTs reported short-term effects (up to 12 weeks).

Table 7 Summary of the effects of an increased intake of legumes on systolic blood pressure in people with type 2 diabetes: RCTs from the SR of Bielefeld et al.[8]

RCT; Study duration	**Jenkins, 2012[14]; 12 weeks**	**Hosseinpour-Niazi, 2015[18]; 8 weeks**
Number of participants in intervention (i) and control (c) group	i: 60 c: 61	i: 31 c: 31
Study design	Parallel RCT	Crossover RCT; washout 4 weeks
Diet of intervention (i) and control (c) group	i: 190 g/day cooked legumes c: High wheat fibre diet. Isocaloric	i: cooked mixed legumes 3 cups/ week c: red meat 2 servings for 3 times a week Isocaloric
Between-group mean difference	-4.5 mmHg (95%CI: -7.0, -2.1)	0.0 mmHg; *p-value* 0.90
Study population	People diagnosed with type 2 diabetes; BMI[a]: 31 (i) and 30 (c) kg/m^2; men and women; diabetes duration[a]: 9 years; diabetes medications[b]: oral agents; Canada.	People with type 2 diabetes; overweight; men and women; diabetes duration[a]: NR; diabetes medications[b]: not reported, insulin users excluded; Iran.

BMI: body mass index; c: control group; i: intervention group; NR: not reported; RCT: randomised controlled trial; SR: systematic review.

[a] BMI and diabetes duration values represent the average in the study population.
[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

Table 8 Summary of the effects of an increased intake of legumes on systolic blood pressure in people with type 2 diabetes: individual recent RCT.

RCT; Study duration	Ward, 2020[10]; 8 weeks
Number of participants in intervention (i) and control (c) group	i: 17 c: 17
Study design	Crossover RCT; 8 weeks washout
Diet of intervention (i) and control (c) group	i: Lupin flour-enriched foods (~45 g/d lupin flour) c: Placebo: same foods without lupin flour No statistically significant difference in energy intake between i and c
Between-group mean difference	-0.41 mmHg; *p-value* 0.33
Study population	People diagnosed with type 2 diabetes; BMI[a]: 29 kg/m^2; men and women; diabetes duration[a]: 5 years; diabetes medications[b]: oral agents; Australia.

BMI: body mass index; c: control group; i: intervention group; RCT: randomised controlled trial.

[a] BMI and diabetes duration values represent the average in the study population.
[b] Diabetes medications represent the types of medications that were used among the participants (it does not mean that *all* participants used those medications).

The Committee concluded the following:

There is too little research to draw conclusions regarding the effects of consumption of legumes compared to control foods without legumes on systolic blood pressure in people diagnosed with type 2 diabetes.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are 3 RCTs with more than 90 participants included in the evaluation, which excludes a conclusion with strong evidence.
2. There is moderate heterogeneity in directions of effects between RCTs. The largest study, with longest duration and with a low risk of bias (Jenkins et al.[14]) showed a greater reduction in systolic blood pressure with legume intake than with control foods. The other two RCTs did not find statistically significant differences in effects on systolic blood pressure. In one of the RCTs, the direction of the effect also pointed towards a reducing effect on systolic blood pressure with the diets high in legumes. However, that study was very small in terms of sample size (n=17, with crossover design) and used processed instead of whole legumes. Also, the Committee notes that the evaluated studies may have been underpowered to detect effects on blood pressure since blood pressure is known to have large variations during the day. Based on those considerations, the Committee concluded there is too little research.

Explanation:

Study characteristics and main effects

The Committee did not find any MAs of RCTs on the effect of an increased intake of legumes on systolic blood pressure in people with type 2 diabetes but one SR was found. In the SR of Bielefeld et al.[8], two RCTs were included that addressed effects on systolic blood pressure.
In addition, one recently published RCT was found, of Ward et al.[10], making a total of 3 RCTs.

All three RCTs were already described in the evaluations of HbA1c and/or fasting blood glucose (Sections 3.1.1 and 3.1.2). Jenkins et al.[14] found a statistically significant 4.5 mmHg greater reduction in systolic blood pressure in the intervention group (cooked legumes diet) compared to the control group (wheat fibre diet). Hosseinpour-Niazi et al.[18] did not find differences in effects on systolic blood pressure in the intervention (cooked mixed legumes) compared to the control (red meat) group.
Ward et al.[10] reported a greater reduction in systolic blood pressure in the intervention (lupin flour-enriched foods) compared to the control (similar foods not enriched with lupin flour) group. However, this difference was not statistically significant. The small size of the trial in terms of number of participants included may have contributed to the lack of statistical difference in effect.

Risk of bias

Bielefeld et al.[8] scored the RCTs of Jenkins et al.[14] and Hosseinpour-Niazi et al.[18] as low risk of bias. The recent RCT of Ward et al.[10] was also judged as low risk of bias.

Overall quality of the evidence

Bielefeld et al.[8] did not address the overall quality of the evidence for systolic blood pressure.

Funding

The funding sources of the evaluated studies and conflicts of interests of the authors are presented in **Annex C.** Jenkins et al.[14] reported funding by the Saskatchewan Pulse Growers. The involvement of the funder was not reported and therefore the impact on the study findings remains unclear. For the other studies, no notable funding sources were reported.

Retention rates and compliance

Where reported, retention rates varied from approximately 80 to 90%. In addition, where reported, the participants were compliant with the dietary intervention, suggesting this likely did not impact the study findings.

Summary

Three RCTs evaluated the differences in effects of diets high in legumes compared to control diets on changes in systolic blood pressure. One

RCT reported a greater reduction in systolic blood pressure with legume intake than with control foods. The other two RCTs did not find statistically significant differences in effects on systolic blood pressure. There were differences in type and dosages of the intervention and control diets and in study durations, which may have contributed to differences in results between studies. All RCTs were scored low risk of bias. Where reported, the compliance was overall good and likely did not affect the results.

3.1.5 LDL cholesterol

The Committee concluded the following:

There is too little research to draw conclusions regarding the effects of consuming legumes compared to control foods without legumes on LDL cholesterol in people diagnosed with type 2 diabetes.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:
There are no MAs that address effects of legume consumption on LDL cholesterol. There is one SR that includes one RCT, and one individual RCT, that address effects on LDL cholesterol. That is too little evidence to base conclusions on.

Explanation:

The Committee did not find any MA of RCTs on the effect of an increased intake of legumes on LDL cholesterol in people with type 2 diabetes but one SR was found. In the SR of Bielefeld et al.[8], one RCT (Hosseinpour-Niazi et al.[18]) was included that addressed effects on LDL cholesterol. That study found a statistically significant 0.18 mmol/L greater reduction of LDL cholesterol in the legume-based diet compared to control diet. Also, there was one recently published RCT found (Ward et al.[10]). That study found no differences in change of LDL cholesterol. Both RCTs have been described above. Two RCTs provide too little evidence for drawing conclusions on effects of legume intake on LDL cholesterol.

3.2 Evidence from prospective cohort studies

The scientific evidence for associations of legume consumption with long-term health outcomes in people with type 2 diabetes is described in Table 9.

Table 9 Summary of associations of legume consumption with risks of CVD, cancer and all-cause mortality in people with type 2 diabetes: prospective cohort studies.

Study; Study duration	Nöthlings, 2008[11]; 9 years[a]	Papandreou, 2019[12]; 6 years[c]
Cohort name	EPIC: Pooled analysis of 21 cohorts	PREDIMED
Exposure	Legume consumption, including soy	Legume consumption, excluding soy
Dietary assessment method	Validated country-specific dietary questionnaire at baseline, either quantitative dietary questionnaires with individual portion sizes or semi-quantitative food frequency questionnaires, or both.	Validated 137-item semi-quantitative food frequency questionnaire at baseline and yearly during follow-up (cumulative average from baseline to the last FFQ before death was used for analysis). Data on legume consumption were derived using four items: lentils, chickpeas, dry beans and fresh peas.
Number of participants; number of cases	10,449 participants; CVD mortality: 517 Cancer mortality: 319 Total mortality: 1,346	7,212 participants; CVD mortality: 103 Cancer mortality: 169
Strength of the association: HR/RR (95%CI)	Per 20 g/d higher legume consumption: CVD MORTALITY: 0.72 (0.60, 0.88)[b] CANCER MORTALITY: 1.09 (0.96, 1.24)[b] TOTAL MORTALITY: 0.93 (0.86, 1.01)[b]	Highest versus lowest tertile of legume consumption: CVD MORTALITY: 1.61 (0.87-2.96)[d], p- linear trend 0.10 CANCER MORTALITY: 0.51 (0.27-0.93)[d], p- linear trend 0.03
Study population	Participants with self-reported diabetes (type 1 or 2); diabetes duration: NR; men and women; BMI: 29 ± 5 kg/m^2; diabetes medication: insulin (21%); Europe	Participants with type 2 diabetes; diabetes duration: NR; men and women; BMI: NR; diabetes medication: NR; Europe

BMI: body mass index; CVD: cardiovascular disease; EPIC: European Prospective Investigation into Cancer and Nutrition; HR: hazard ratio; NR: not reported; PREDIMED: PREvención con DIeta MEDiterránea; RR: risk ratio.

[a] Mean (± standard deviation);
[b] Associations were stratified by age and study centre and adjusted for sex, smoking status, self-reported heart attack at baseline, self-reported hypertension at baseline, self-reported cancer at baseline, waist-to-hip ratio, insulin treatment, age at diabetes diagnosis, energy intake and alcohol intake;
[c] Median;
[d] Associations were stratified by recruitment centre and adjusted for age, sex, intervention group, prevalence of hypertension, hypercholesterolemia, baseline BMI, smoking status, educational level, physical activity, use of antihypertensive medication, use of antidiabetic agents, statin use, alcohol intake and the 13-point screener (excluding legumes) of Mediterranean diet adherence.

The Committee concluded the following:

Prospective cohort studies show that higher consumption of legumes is associated with lower risk of CVD mortality in people with type 2 diabetes. The evidence is limited.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are no MAs of prospective cohort studies that address associations of legume consumption with risk of CVD mortality. There is one pooled analysis of 21 cohorts and one individual cohort study, with in total >500 CVD cases, that address this topic. This is the first step required to mark the evidence as strong. However, there were other considerations that lead to the conclusion of limited evidence, as described below.
2. The extent of heterogeneity between the cohort studies contributing to the pooled analysis is unknown. There is heterogeneity in the directions of the associations between the result of the pooled analysis and individual cohort study. A beneficial association was found in the pooled

analysis. This was not supported by the individual cohort study (that found a tendency towards an unfavourable association). The Committee noted several methodological concerns with the individual cohort study, which may have influenced the result. Therefore, the Committee primarily based its conclusion on the pooled analysis. Due to the heterogeneity between the two studies, the evidence was judged as limited (instead of strong).

There is inconclusive evidence regarding the association of legume consumption with risk of cancer mortality in people with type 2 diabetes.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are no MAs of prospective cohort studies that address associations of legume consumption with risk of cancer mortality. There is one pooled analysis of 21 cohorts and one individual cohort study, with almost 500 cancer cases, that addresses this topic. This is the first step required to mark the evidence as strong. However, the evidence was judged as inconclusive, as described below.
2. There is heterogeneity in the direction of the association. The pooled analysis showed no association between legume consumption and risk of cancer mortality, whereas the individual study showed an inverse (beneficial) association. The Committee noted several methodological concerns with the individual cohort study, which may have influenced the study findings. Due to the heterogeneity, the Committee concluded the evidence is inconclusive.

Prospective cohort studies show that higher consumption of legumes is associated with lower risk of all-cause mortality in people with type 2 diabetes. The evidence is limited.

The following considerations were made by the Committee, following the steps of the decision tree, to come to this conclusion:

1. There are no MAs of prospective cohort studies that address associations of legume consumption with risk of total mortality. There is one pooled analysis of 21 cohorts, with more than 500 mortality cases, that addresses this topic. This is the first step required to mark the evidence as strong. However, there were other considerations to mark the evidence as limited.
2. There is an inverse association of legume consumption with total mortality. The extent of heterogeneity between the cohort studies contributing to the pooled analysis is unknown. All cohorts in this pooled analysis are from the same consortium (EPIC) and therefore any dependency between cohorts cannot be ruled out. Because there is no other study that supports the result of the pooled analysis, the evidence was considered limited.

Explanation:
One pooled analysis of 21 cohorts and one individual cohort study were found that addressed the associations of legume consumption with mortality from CVD and cancer.

The study by Nöthlings et al.[11] is a pooled analysis of 21 cohorts from the European Prospective Investigation into Cancer and Nutrition (EPIC) study, covering nine European countries. One of its aims was to examine the association of legume consumption with risk of total and cause-specific mortality in people with diabetes. A total of 10,449 European individuals with self-reported diabetes (type 1 and type 2) at baseline were included. After a mean of 9 years follow-up (range: 1 to 14 years), 1346 fatal events, of which 517 fatal CVD events and 319 fatal cancer events, were recorded. Soy products were included in the legumes food group.

This study showed that a higher consumption of legumes associated with reduced risk of all-cause and CVD mortality but not cancer mortality. For all-cause mortality, the association was borderline significant when analysed per 20 g/d increment. When analysed in quartiles of intake, people in the highest compared to lowest quartile of legume consumption (32 vs. 0 g/d) had a statistically significant 28% lower risk of all-cause mortality. Sensitivity analyses were performed that included only participants diagnosed with diabetes after the age of 40. This is expected to exclude all people with type 1 diabetes. The sensitivity analyses were performed for the combined exposure of fruit, vegetables and legume consumption. The RR for all-cause mortality, per 80 g/d higher intake, was 0.95 (95%CI 0.90–1.00), which was essentially the same as for the overall group (RR 0.94, 95%CI 0.90–0.98). Also, stronger associations with all-cause mortality were found among those not treated with insulin (RR 0.90, 95%CI 0.84–0.96) than those treated with insulin (RR 0.96, 95%CI 0.87–1.06).

The study of Papandreou et al.[12] included 7,212 individuals from the PREDIMED trial. The PREDIMED trial was conducted among older men (55-80 years) and women (60-80 years) who were allocated to a Mediterranean diet supplemented with extra-virgin olive oil, a Mediterranean diet supplemented with mixed nuts, or a control diet consisting of advice to reduce the consumption of all sources of fat. The study population was at high risk of CVD. Participants were eligible if they had either type 2 diabetes or at least three CVD risk factors, such as hypercholesterolemia. The data from the PREDIMED trial were analysed as observational prospective cohort study by Papandreou et al. They performed subgroup analyses among people with type 2 diabetes. Soy was not included in the definition of legumes.

During a median follow-up of 6 years, 103 CVD deaths and 169 cancer deaths were recorded in the total study population. The number of people with type 2 diabetes included in the analysis was not reported and neither was the number of events among people with type 2 diabetes. In the report of the main RCT results, approximately half of the study population had type 2 diabetes.[19] In the subgroup of people with type 2 diabetes, total legume consumption was non-significantly associated with a higher risk of CVD mortality (HR for highest versus lowest tertile 1.61, 95%CI: 0.87-2.96) and with a statically significant lower risk of cancer mortality (HR for highest versus lowest tertile 0.51, 95%CI 0.27-0.93). In the total study population, the lower cancer mortality was particularly seen for consumption of chickpeas and the higher CVD mortality was particularly seen for consumption of dry beans (associations with subtypes of legumes were not investigated among people with type 2 diabetes). Possible explanations for the unexpected increased CVD risk were given by the authors: 1) there was a particularly strong association of dry bean consumption with spontaneous cardiac arrest. Spontaneous cases of cardiac arrest, caused by gastric dilatation and elevated abdominal pressure, could be caused by binge eating or by the dyspepsia and discomfort associated with cowpeas and dry beans in general, and 2) there may be residual confounding since dry beans are often consumed in dishes with red and/or processed meat.

The Committee had some concerns regarding the design of this study. It noted that the observational analysis was conducted within an RCT that aimed to adapt dietary intake, including legume intake. The observational analysis was conducted over all intervention arms, without the interaction with the intervention arms being tested.

3.3 Summary of conclusions

Table 10 Overview of conclusions regarding relationships (effects and associations) of legume consumption with health outcomes in people diagnosed with type 2 diabetes.

Health outcome[a]	Study design	Conclusion
HbA1c	RCTs	A higher intake has a reducing effect; limited evidence
Fasting blood glucose	RCTs	A higher intake has a reducing effect; limited evidence
Body weight	RCTs	A higher intake has a reducing effect; limited evidence
Systolic blood pressure	RCTs	Too little research
LDL cholesterol	RCTs	Too little research
CVD mortality	Cohort studies	A higher intake associates with a lower risk; limited evidence
Cancer mortality	Cohort studies	Inconclusive evidence
All-cause mortality	Cohort studies	A higher intake associates with a lower risk; limited evidence

[a] The table contains the health outcomes for which (relevant) studies were found. For the health outcomes that are not listed in the table, no (relevant) studies were found.

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annexes

A search strategy, study selection and flow diagrams

Meta-analyses and systematic reviews
The Committee used the following searches on 20 (PubMed) and 29 (Scopus) July 2020 to find relevant SR and MA on carbohydrate containing food sources and dietary fibre and health outcomes among people with type 2 diabetes:

Pubmed
("diabetes mellitus, type 2"[MeSH] OR Diabet*[tiab] OR T2DM[tiab] OR NIDDM[tiab]) AND (("Dietary Fiber"[Mesh] OR "Dietary Carbohydrates"[Mesh] OR "Starch"[Mesh] OR "Polysaccharides"[Mesh] OR "Fructans"[Mesh] OR "Inulin"[Mesh] OR "Dietary sugars"[Mesh] OR (dietary[tiab] AND (fiber*[tiab] OR fibre*[tiab] OR carbohydrates[tiab] OR starch*[tiab] OR fructan[tiab] OR inulin[tiab] OR sugar*[tiab]))) OR (("edible grain"[MeSH] OR "edible grain"[tiab] OR cereals[tiab] OR "Whole Grains"[Mesh] OR grain*[tiab] OR wheat*[tiab] OR oat[tiab]) OR (fruit[MeSH] OR fruit[tiab] OR fruits[tiab]) OR (vegetables[MeSH] OR vegetables[tiab]) OR (((sugars[MeSH] OR sugars[tiab] OR sugar[tiab] OR sweetened[tiab] OR sweetener[tiab]) AND (beverages[MeSH] OR beverages[tiab] OR drink*[tiab] OR juice*[tiab] OR soda*[tiab]))) OR (fabaceae[MeSH] OR fabaceae[tiab] OR legume[tiab] OR legumes[tiab] OR bean*[tiab] OR "Soybean Proteins"[Mesh]OR soy[tiab] OR soya[tiab]))) AND (Systematic review[publication type] OR Meta-analysis[publication type] OR review[tiab] OR "meta-analysis"[tiab] OR meta analysis[tiab] OR metaanalysis[tiab] OR quantitative review[tiab] OR quantitative overview[tiab] OR systematic review[tiab] OR systematic overview[tiab] OR methodologic review[tiab] OR methodologic overview[tiab]).

Limit: after 2000 + English

Scopus
((KEY("diabetes mellitus, type 2") OR TITLE-ABS-KEY (t2dm) OR TITLE-ABS-KEY (niddm))) OR (TITLE-ABS ("diabetes mellitus, type 2") OR TITLE-ABS (diabet*) OR TITLE-ABS (t2dm) OR TITLE-ABS (niddm)) AND (TITLE-ABS-KEY ("Dietary Fiber") OR TITLE-ABS-KEY ("Dietary Carbohydrates") OR TITLE-ABS-KEY ("Starch") OR TITLE-ABS-KEY ("Polysaccharides") OR TITLE-ABS-KEY ("Fructans") OR TITLE-ABS-KEY ("Inulin"))) OR ((TITLE-ABS (dietary)) AND (TITLE-ABS (fiber*) OR TITLE-ABS (fibre*) OR TITLE-ABS (carbohydrates) OR TITLE-ABS (starch*) OR TITLE-ABS (fructan) OR TITLE-ABS (inulin) OR TITLE-ABS (sugar))) AND ((TITLE-ABS-KEY ("edible grain")) OR ((TITLE-ABS-KEY (cereals) OR KEY ("Whole Grains") OR TITLE (grain*) OR ABS (grain*) OR TITLE (wheat*) OR ABS (wheat*) OR TITLE (oat) OR ABS (oat))) OR (KEY (fruit) OR TITLE-ABS (fruit) OR TITLE-ABS (fruits)) OR (KEY (vegetables) OR TITLE-ABS (vegetables)) OR (KEY (sugars) OR TITLE-ABS

(sugar) OR TITLE-ABS (sugars) OR TITLE-ABS (sweetened) OR TITLE-ABS (sweetener) OR KEY (beverages) OR TITLE-ABS (beverages) OR TITLE-ABS (drink*) OR TITLE-ABS (juice*) OR TITLE-ABS (soda*) OR KEY (fabaceae) OR TITLE-ABS (fabaceae) OR TITLE-ABS (legume) OR TITLE-ABS (legumes) OR KEY ("Soybean Proteins") OR TITLE-ABS (soy) OR TITLE-ABS (soya)) AND ((TITLE-ABS-KEY ("Systematic review") OR TITLE-ABS-KEY ("Meta-analysis"))) OR (TITLE-ABS (review) OR TITLE-ABS (meta-analysis) OR TITLE-ABS (meta analysis) OR TITLE-ABS ("quantitative review") OR TITLE-ABS ("quantitative overview") OR TITLE-ABS ("systematic overview") OR TITLE-ABS ("methodologic review") OR TITLE-ABS ("methodologic overview")).

Limit: after 2000 + English

In total, 2,054 articles were found in PubMed and 3,887 in Scopus. After removal of duplicates, 4,527 articles remained and were screened for title and abstract. A total of 172 articles was selected for full text screening and 19 articles were selected for the evaluation of carbohydrate containing food sources and dietary fibre.

Of these 28 articles, 1 article was relevant for the evaluation of legumes. In addition, the dietary guidelines of the Nederlandse Diabetes Federatie (NDF)[20] pointed out an additional, more recent SR into legumes (Bielefeld et al.[8]). This SR was also included in the evaluation. No articles relevant for soy were found.

The following two SRs for the evaluation of legumes were found:

- Bielefeld et al., 2020[8]
- Ferreira et al., 2020[21]

Bielefeld et al.[8] included more RCTs than Ferreira et al.[21] Since all RCTs evaluated by Ferreira et al.[21] were already included by Bielefeld et al.[8],the SR of Ferreira et al.[21] was discarded. Effect estimates were reported for HbA1c and fasting blood glucose in the SR of Bielefeld et al.[8] Effects on LDL cholesterol, body weight and systolic blood pressure were looked up in the original RCT reports.

Randomised controlled trials

RCTs published after the inclusion date of the most recent SR/MA on legumes were searched on 31 August (PubMed) and 1 September (Scopus) 2020. Only health outcomes that were already covered in the selected SR/MA were included in the search. The following searches were performed:

Pubmed

("diabetes mellitus, type 2"[MeSH] OR Diabet*[tiab] OR T2DM[tiab] OR NIDDM[tiab]) **AND** ((dietary[tiab] AND pulses[tiab]) OR legumes[tiab] OR bean[tiab] OR beans[tiab] OR chickpea[tiab] OR pea[tiab] OR lentil[tiab]

OR cowpea[tiab] OR fababean[tiab] OR lupin[tiab]) **AND** (“Cardiovascular Diseases”[Mesh] OR “Heart Diseases”[Mesh] OR “Stroke”[Mesh] OR “Heart Failure”[Mesh] OR Coronary disease[tiab] OR stroke[tiab] OR CVA[tiab] OR Cerebrovascular Accident[tiab] OR Cardiac Failure[tiab] OR Heart Decompensation[tiab] OR heart failure[tiab] OR Myocardial Failure[-tiab] OR glycemic control[tiab] OR glycaemic control[tiab] OR glycemia[-tiab] OR glycaemia[tiab] OR glucose[tiab] OR “Glycated Hemoglobin A”[Mesh] OR HbA1c[tiab] OR Glycated Hemoglobin[tiab] OR Glycosylated Hemoglobin[tiab] OR “Body Mass Index”[Mesh] OR BMI[tiab] OR “Blood Pressure”[Mesh] OR blood pressure[tiab] OR Diastolic Pressure[tiab] OR Systolic Pressure[tiab] OR pulse pressure[tiab] OR “Body Weight”[Mesh] OR weight[tiab]) **AND** (“Clinical Trials as Topic”[Mesh] OR “Clinical Trial” [publication type] OR “Cross-Over Studies”[Mesh] OR “Double-Blind Method”[Mesh] OR “Single-Blind Method”[Mesh] OR “Controlled Before-After Studies”[Mesh] OR “Historically Controlled Study”[Mesh] OR rand-omized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled*[tiab] OR placebo[tiab] OR clinical trial[tiab] OR trial[tiab] OR intervention[tiab])

Limit: after 2018

Scopus

(KEY(diabetes AND mellitus,type 2) OR TITLE-ABS (diabetes AND mellitus, AND type 2) OR TITLE-ABS (diabet*) OR TITLE-ABS (t2dm) OR TITLE-ABS (niddm)) **AND** (TITLE-ABS (dietary) AND TITLE-ABS (pulses) OR TITLE-ABS (legumes) OR TITLE-ABS (bean) OR TITLE-ABS (beans) OR TITLE-ABS (chickpea) OR TITLE-ABS (pea) OR TITLE-ABS (lentil) OR TITLE-ABS (cowpea) OR TITLE-ABS (fababean) OR TITLE-ABS (lupin)) AND (TITLE-ABS-KEY(cardiovascular AND diseases) OR TITLE-ABS-KEY (heart AND diseases) OR KEY (stroke) OR TITLE-ABS-KEY (heart AND failure) OR TITLE-ABS (coronary AND disease) OR TITLE-ABS (stroke) OR TITLE-ABS (cva) OR TITLE-ABS (cerebrovas-cular AND accident) OR TITLE-ABS (cardiac AND failure) OR TITLE-ABS (heart AND decompensation) OR TITLE-ABS (heart AND failure) OR TITLE-ABS (myocardial AND failure) OR TITLE-ABS (glycemic AND control) OR TITLE-ABS (glycaemic AND control) OR TITLE-ABS (glycemia) OR TITLE-ABS (glycaemia) OR TITLE-ABS (glucose) OR KEY (glycated AND hemoglobin AND a) OR TITLE-ABS (hba1c) OR TITLE-ABS (glycated AND hemoglobin) OR TITLE-ABS (glycosylated AND hemoglobin) OR KEY (body AND mass AND index) OR TITLE-ABS (bmi) OR KEY (blood AND pressure) OR TITLE-ABS (blood AND pres-sure) OR TITLE-ABS (diastolic AND pressure) OR TITLE-ABS (systolic AND pressure) OR TITLE-ABS (pulse AND pressure) OR KEY (body AND weight) OR TITLE-ABS (weight) **AND** (((TITLE-ABS-KEY (clinical AND trials AND as AND topic) OR TITLE-ABS (clinical AND trial) OR TITLE-ABS-KEY (cross-over AND studies) OR TITLE-ABS-KEY (double-blind AND method) OR TITLE-ABS-KEY (single-blind AND method) OR TITLE-ABS-KEY (controlled AND before-after AND studies) OR TITLE-ABS-KEY (historically AND controlled AND study)) OR (TITLE-ABS (randomised)

OR TITLE-ABS (randomized) OR TITLE-ABS (rct) OR TITLE-ABS (controlled*) OR TITLE-ABS (placebo) OR TITLE-ABS (clinical AND trial) OR TITLE-ABS (trial) OR TITLE-ABS (intervention))).

Limit: after 2018

A total of 47 articles were found in PubMed and 47 in Scopus. After removal of the duplicates, 70 articles remained and were screened for title and abstract. In total, 12 articles were selected for full text screening, and based on this, two recent RCTs were selected.

The Committee selected two RCTs for the evaluation of legumes:
- Lui et al., 2018[9]
- Ward et al., 2020[10]

The RCT of Liu et al.[9] was used for the evaluation of effects on HbA1c, fasting blood glucose and body weight. The RCT of Ward et al.[8] was used for the evaluation of effects on fasting blood glucose, body weight and LDL cholesterol.

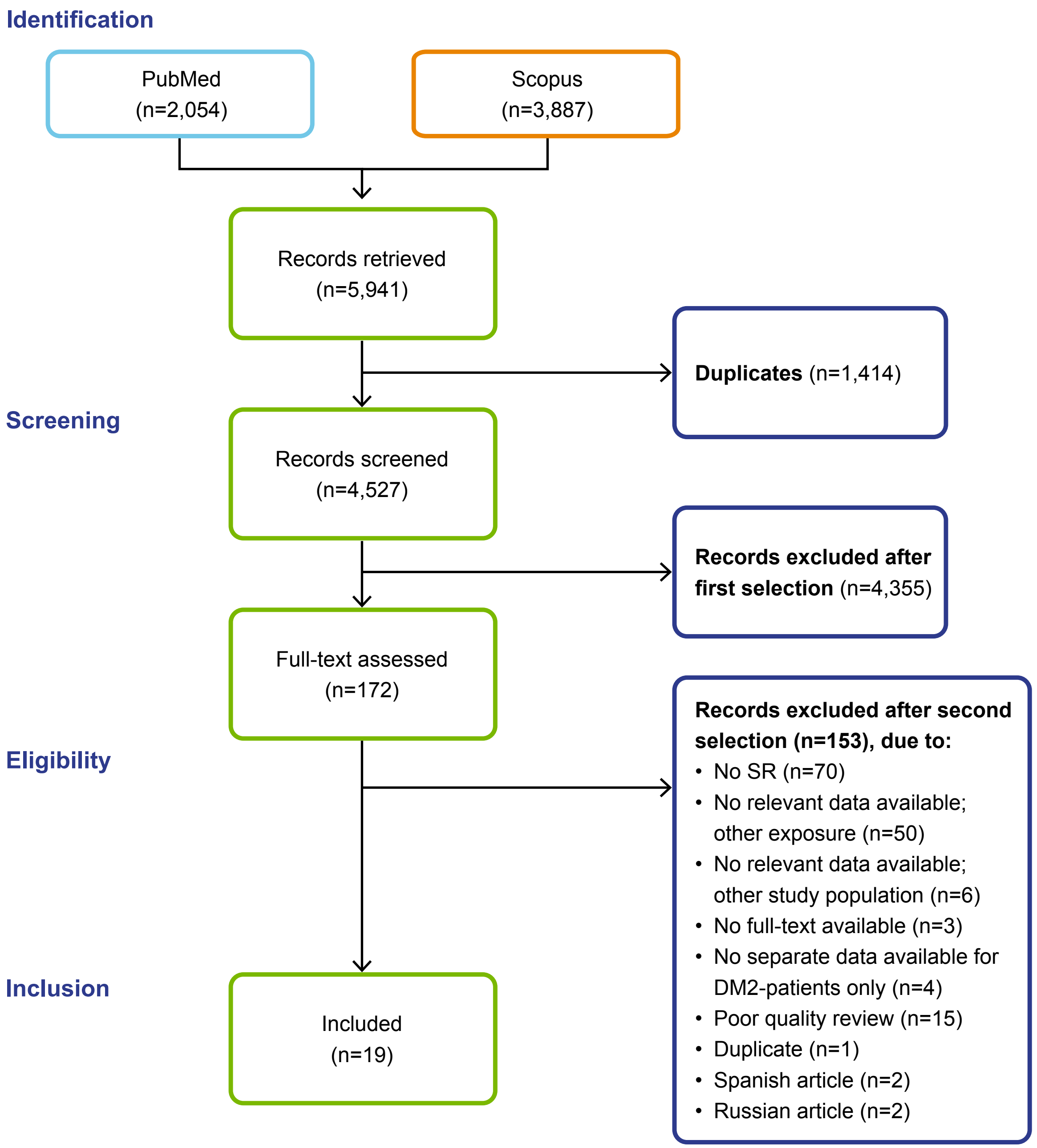
Prospective cohort studies

Since none of the selected MAs and SRs reported evidence from prospective cohort studies, the existing dietary diabetes guidelines of the following organizations were searched for individual cohort studies with respect to associations of soy and legume consumption on health outcomes:
- Nederlandse Diabetes Federatie (NDF), 2020[20]
- European Association for the Study of Diabetes (EASD) & European Society of Cardiology (ESC), 2020[22]
- American Diabetes Association (ADA) 2019[23]
- Diabetes UK, 2018[24]
- Diabetes Canada, 2018[25]
- Swedish Council, 2010[26]

One pooled analysis of prospective cohort study was found in the guideline of the Swedish Council (Nöthlings et al., 2008[11]). The study included data on the associations of legume intake with mortality from all causes, cardiovascular disease and cancer. Next, articles citing this study were searched in PubMed on 9 December 2020. This yielded 53 hits. Of those, 1 prospective cohort study was selected (Papandreou et al., 2019[12]). That study included data on the associations of legume intake with mortality from cardiovascular disease and cancer in subgroup analyses among people with type 2 diabetes. No prospective cohort studies were found for soy. Thus, one pooled analysis of and one individual prospective cohort study were selected by the committee for legumes:
- Nöthlings et al., 2008[11]
- Papandreou et al., 2019[12]

Flowchart for the selection of systematic reviews (SRs) and meta-analyses (MAs)

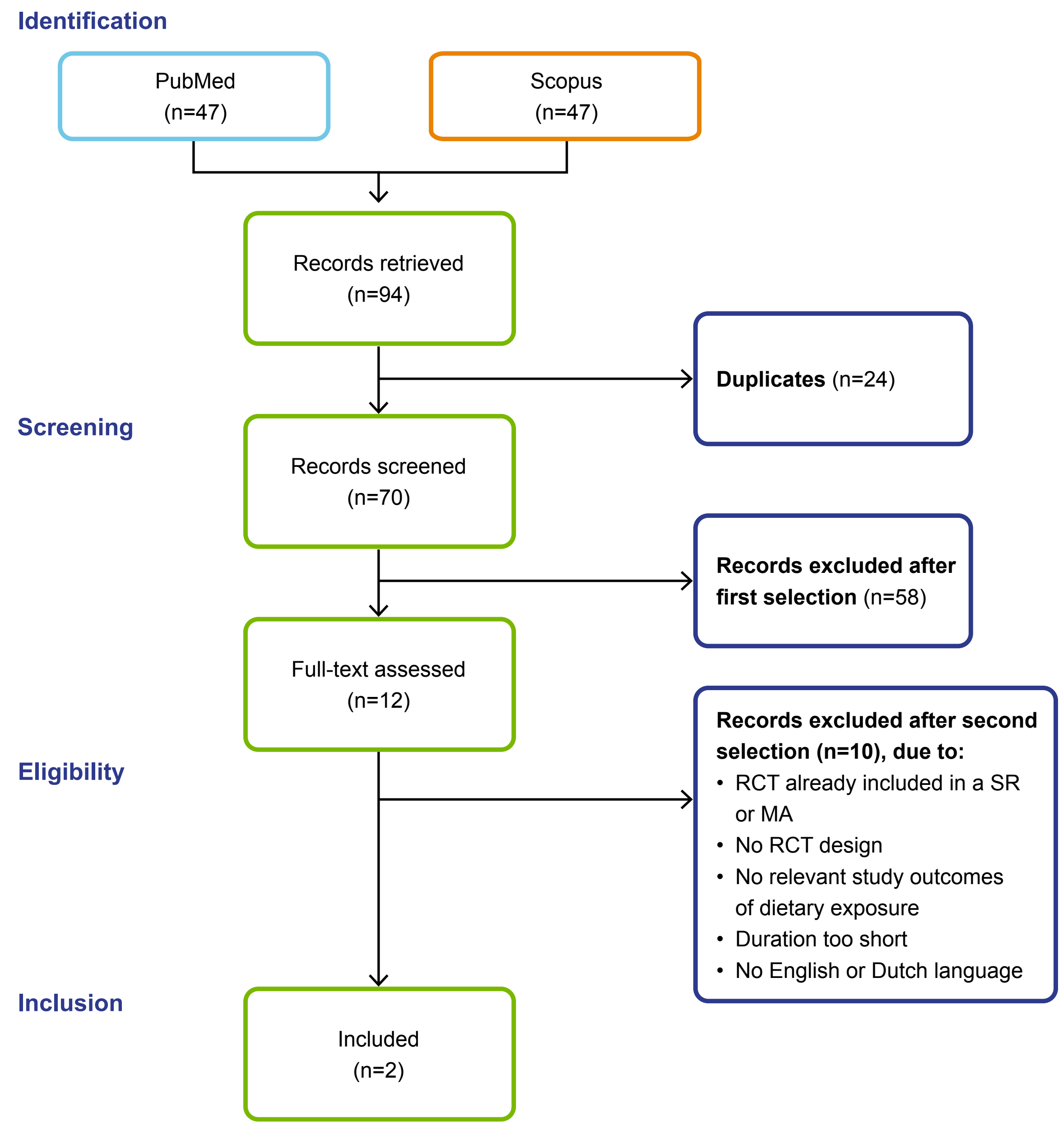
Carbohydrate food sources and dietary fibre



DM2: type 2 diabetes; SR: systematic review.

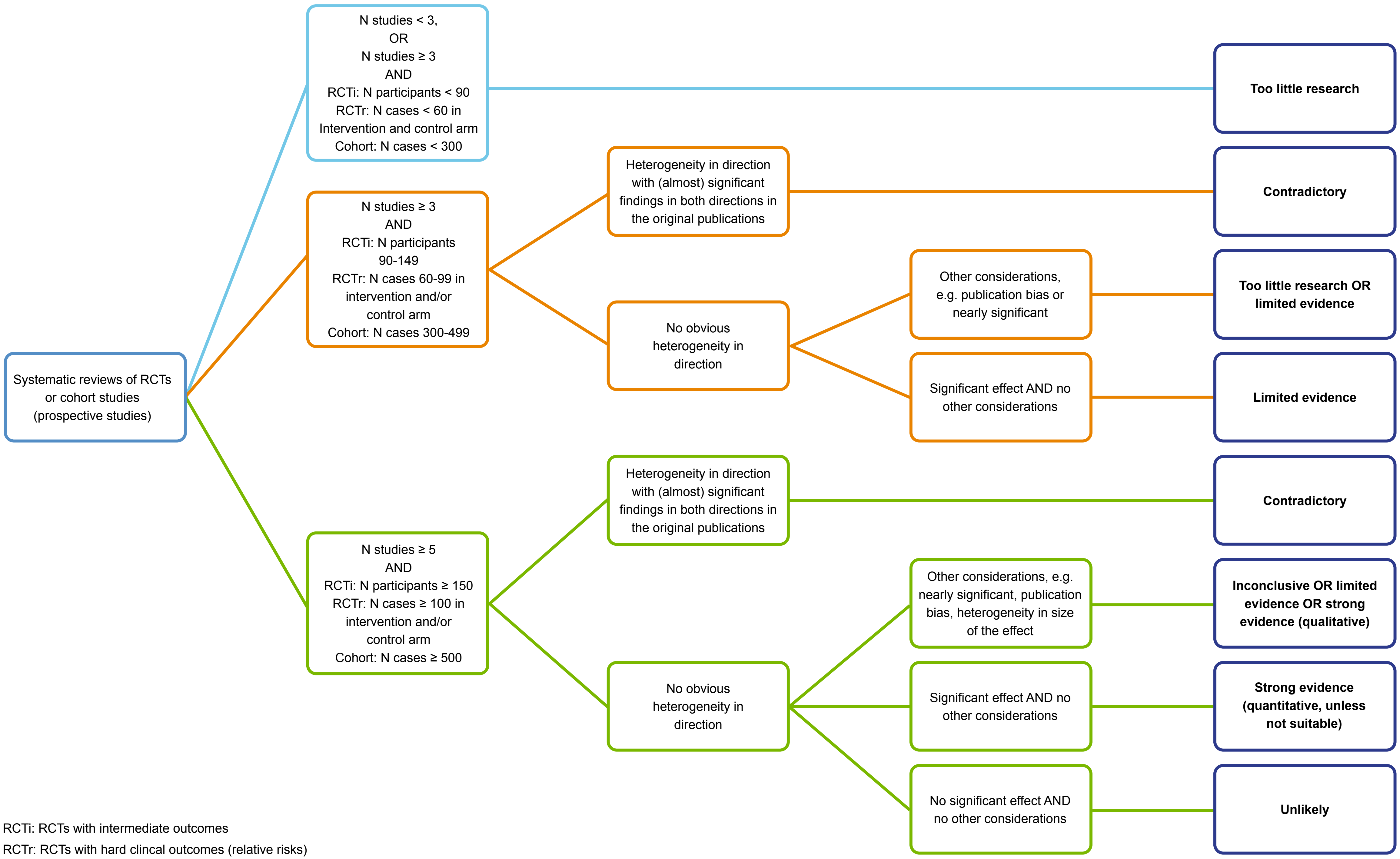
Flowchart for the selection of randomized controlled trails (RCTs)

Legumes and DM2



MA: meta-analysis; RCT: randomized controlled trial; SR: systematic review.

B decision tree



RCTi: RCTs with intermediate outcomes
RCTr: RCTs with hard clincal outcomes (relative risks)

C funding sources and conflicts of interest regarding the articles used in this background document

In the table below, the funding sources of the studies listed in this background document and conflicts of interests of authors contributing to those studies are reported.

Study: First author, year	Funding of the work	Conflicts of interest of authors
Bielefeld, 2020[8]	The research was supported by the Grains & Legumes Nutrition Council, a not-for-profit charity.	One of the authors declared to be employed by the Grains & Legumes Nutrition Council. The other authors declared to have no conflicts of interest.
Jenkins, 2012[14]	The work was supported by ABIP through the PURENet and the Saskatchewan Pulse Growers.	Some of the authors (including the first author) reported to have received research grants, travel funding, consultant fees, or honoraria or to have served on the scientific advisory boards of (food) companies and (collective) boards, foundations, commissions, funds or councils of food companies. These include (not an exhaustive list) Kellogg's, Quaker Oats, Procter & Gamble, Coca-Cola, Saskatchewan Pulse Growers, The Canola and Flax Councils of Canada.
Hassanzadeh-Rostami, 2019[15]	The study was financially supported by Shiraz University of Medical Sciences, Shiraz, Iran.	The authors declared to have no conflicts of interests.
Simpson, 1981[16]	No full text was available and no information was provided in the abstract.	No full text was available and no information was provided in the abstract.
Liu, 2018[9]	The study was supported by the earmarked fund for the Modern Agro-Industry Technology Research System and the Sci & Tech Innovation Program of CAAS.	The authors declared to have no conflicts of interests.
Ward, 2020[10]	The study was funded by a Royal Perth Hospital Medical Research Foundation Grant. Study foods were prepared and supplied by several food companies.	The authors declared to have no conflicts of interests.
Shams, 2010[17]	No information was provided.	No information was provided.
Hosseinpour-Niazi, 2015[18]	The study was funded by a grant from the Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran.	The authors declared to have no conflicts of interests.
Nothlings, 2008[11]	The study was supported by the Community (Directorate-General SANCO: Directorate X-Public Health and Risk Assessment). Financial support for the EPIC study came from the European Commission, national ministries (e.g. Spanish Ministry of Health, Greek Ministry of Education and Dutch Ministry of Public Health, Welfare and Sports) and research councils (e.g. Medical research Council UK, Italian Association for Research on Cancer and Danish Cancer Society).	The authors declared to have no conflicts of interests.
Papandreou, 2019[12]	The work was supported by the Instituto de Salud Carlos III (ISCIII) of Spain and by governmental grants. The olive oil and nuts were donated by olive oil or nut-related commissions, companies or foundations.	The authors declared to have no conflicts of interests.

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is "to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research..." (Section 22, Health Act).
The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.
Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

This publication can be downloaded from www.healthcouncil.nl.

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