Dietary fibre

No. 2021/41De, 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

The current 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 dietary fibre intake and health outcomes in adults with type 2 diabetes. It furthermore describes the scientific evidence on this topic and the conclusions that have been drawn by the Health Council's Committee on Nutrition.

1.1 Definition of dietary fibre

Dietary fibre is the collective term for a group of substances that are not digested or absorbed in the human small intestine, but most of which is broken down in the colon by gut microbiota.[2] These substances are very diverse in nature and physiological function. There currently is no international consensus on the definition of dietary fibre. Differences between countries and institutions exist regarding the substances that are considered dietary fibre and definitions have changed in the past years. For this background document the Committee considered all literature that aims to study dietary fibre, despite the definition that was used to determine dietary fibre, which is in line with the approach of the *Dutch dietary guidelines 2015*.[2,3]

1.2 Dietary fibre recommendations and intake in the Netherlands

In its 2006 report, the Health Council of the Netherlands recommends the general Dutch adult population (≥14 years) to consume 3.4 grams of fibre per Megajoule (MJ) or 14 grams of fibre per 1000 kilocalories (kcal), which equates to 30 to 40 grams per day.[4]

Scientific evidence on the health effects of dietary fibre were also used for the development of dietary guidelines for the fibre-rich food groups 'fruits and vegetables' and 'whole grain foods' in the *Dutch dietary guidelines 2015*.[2] These guidelines included:

- Eat at least 200 grams of vegetables and at least 200 grams of fruit daily;
- Eat at least 90 grams of brown bread, wholemeal bread or other whole grain products daily;
- Replace refined cereal products with whole grain products.

These recommendations are applicable to the general population. The Council has not previously made specific dietary recommendations for people with type 2 diabetes.

Data from the most recent Dutch National Food Consumption Survey (2012-2016) shows that the intake of dietary fibre among the general Dutch population aged 19 to 79 years is on average 20 g/day (or 2.3 g/MJ/day). The three main food sources of dietary fibre are: bread, cereals, rice and pasta (42%), vegetables (14%) and fruit, nuts and olives (14%).[5]

1.3 Food-based dietary guidelines

In the current advisory report the Committee evaluates whether or not the *Dutch dietary guidelines 2015*[3] are applicable to adults with type 2 diabetes, or whether certain modifications or additions to the guidelines would be recommendable to further improve the health of those people. In both cases, the guidelines will be food-based. Since dietary fibre is not a food but a nutrient, the Committee did not develop guidelines for dietary fibre itself. Instead, it used the evidence on the health effects of dietary fibre to complement the evidence on the health effects of fibre-rich food groups. The food source of the dietary fibre in the studies determines to which food group(s) this research can be supportive. The current background document describes the scientific evidence on dietary fibre. The scientific evidence on each of the food groups per se is described in separate background documents (e.g. background document *Fruit and Vegetables*[6] and background document *Whole grain foods*[7]).

02 methodology

2.1 Research questions

The current background document on dietary fibre serves the purpose of providing ancillary evidence to answering the broader question of what the relationship is of the fibre-rich food groups of whole grain foods, fruits and vegetables and legumes on health outcomes in people with type 2 diabetes. With respect to dietary fibre, the Committee aimed to answer the following questions:

1. What is the relationship (effect or association) of higher total fibre intake with health outcomes in people with type 2 diabetes?
2. What is the relationship (effect or association) of higher intake of fibre from whole grain products, fruits, vegetables and legumes with health outcomes in people with type 2 diabetes?

The Committee aimed to distinguish between short-term and long-term studies, where possible. In the current background document, studies with a duration of 12 weeks or less were considered short-term studies and the study with a duration of 1 year was considered a long-term study.

2.2 Types of dietary fibre and methods of administration

2.2.1 Dietary fibre types and food sources

Many different types of dietary fibre exist, such as cellulose, pectin, beta-glucan and inulin-type fructan. A food may contain multiple fibre types. Also, one fibre type may be present in a greater amount in one food product compared to the other. For example, pectin is the predominant fibre type in fruits and vegetables, whereas beta-glucan is the predominant fibre type in oats and barley.[8] However, some fibre types are not that food-specific. For example, inulin-type fructans may be present in onions and chicory root (vegetables) but also in wheat and barley (grains). Together, this implies that the relationship of total fibre intake with health outcomes may depend on the type(s) of fibre and their food source. As the *Dutch dietary guidelines 2015* are *food*-based, the Committee aimed to report the effects of fibre intake according to its food source (and not according to the fibre type), where possible.

The Committee excluded studies into the fibre types inulin-type fructan and resistant starch. The first reason for this is that inulin-type fructan and resistant starch are largely used for food fortification and only occur naturally in foods in small amounts. Second, the amount of resistant starch naturally present in foods is largely dependent on the method of preparation, storage and serving temperature[9], limiting the possibility to provide general food-based advice on dietary fibre. The Committee included studies into beta-glucan (provided the intervention was food-based) because the Committee noted that the retrieved studies into the effect of beta-glucan were predominantly oat-based and, therefore, it considered those studies relevant as ancillary evidence for the product group of whole grain foods.

2.2.2 Fibre supplements

Following the approach of the *Dutch dietary guidelines 2015*, the Committee focused on fibres that are naturally present in foods. Guar gums and psyllium are fibre types that are not naturally present in foods, but are used as thickeners or stabilizers, and were therefore disregarded.

In contrast with the approach of the *Dutch dietary guidelines 2015*, in which studies using fibre supplements were included, the current Committee decided to exclude studies using fibre supplements and to include only studies in which the fibre intervention was food-based.
Its two major arguments were the following: first, the effect of isolated and processed fibres might substantially differ from the effect of fibres as part of a food.[10-12] Thus, the results from studies using fibre supplements cannot be simply translated into food-based recommendations. Second, administration of supplements with a high dose of a specific type of fibre might exert unfavourable effects on microbiota and unbalance blood glucose levels.[13] So, the Committee cannot exclude the possibility that harmful off-target effects (i.e. unexpected side effects) of supplements occur when the fibre dose of such supplements far exceeds the usual fibre intake in a population.

2.3 Outcomes

The Committee selected the following health outcomes for this advisory report (for which a motivation is provided in the background document *Methodology for the evaluation of evidence*[14]):

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:

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

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 only included studies with long-term health outcomes.

2.4 Selection and evaluation of literature

A detailed description of the approach used by the Committee for selecting and evaluating the scientific literature is provided in the back-ground document *Methodology for the evaluation of evidence*.[14] In short, the Committee aimed to base its evaluation of scientific literature on systematic reviews (SRs), including meta-analyses (MAs), of randomised controlled trials (RCTs) and/or prospective cohort studies (i.e. prospective cohort studies, nested case-control studies and case-cohort studies) examining the effects or associations of fibre intake with the above-mentioned health outcomes in people with type 2 diabetes. In addition, the Committee searched for more recent individual studies that were not included in the most recent SR or MA. The search strategy, flow diagrams of the literature searches and detailed description of the study selection are provided in **Annex A**.

2.4.1 Selection of randomised controlled trials

The Committee found SRs, including MAs, of RCTs into the effect of total fibre intake and the intake of beta-glucan. However, none of the retrieved MAs included only (or almost only) food-based fibre interventions.
The majority of RCTs in the MAs used fibre supplements to increase the participants' fibre intake. The Committee considered those studies irrelevant for this advisory report. Because no MAs met the Committee's criteria, the Committee decided to evaluate the relevant individual (food-based) RCTs from the SRs and MAs retrieved.

In total, the Committee selected seven RCTs for evaluation (Table 1). The Committee could distinguish two categories of studies, according to the foods by which the increase in fibre intake was achieved:
(1) fibre from whole grain foods[15-19] and (2) total fibre.[20,21] The latter category includes the studies in which fibre intake was increased using multiple food sources. All RCTs examined increased fibre intake in relation to a surrogate outcome including HbA1c, fasting blood glucose, body weight, LDL cholesterol and systolic blood pressure. The Committee did not find RCTs within the pre-specified in- and exclusion criteria for the outcomes of eGFR (surrogate endpoint), any of the specified long-term health outcomes, and diabetes remission or reversion.

Table 1 Overview of randomised controlled trials selected by the Committee for the evaluation of the effect of increased dietary fibre intake on health outcomes, grouped according to the food source of fibre.

Dietary exposure	Health outcome[a]	Randomised controlled trials
Fibre from whole grain foods	HbA1c	Jenkins et al., 2002[15] Kondo et al., 2017[17] Li et al., 2016[18] Stevens et al., 1985[19]
Fibre from whole grain foods	Fasting blood glucose	Jenkins et al., 2002[15] Karlström et al., 1984[16] Kondo et al., 2017[17] Li et al., 2016[18] Stevens et al., 1985[19]
Fibre from whole grain foods	Body weight	Jenkins et al., 2002[15] Kondo et al., 2017[17] Li et al., 2016[18] Stevens et al., 1985[19]
Fibre from whole grain foods	LDL cholesterol	Jenkins et al., 2002[15] Karlström et al., 1984[16] Kondo et al., 2017[17] Li et al., 2016[18]
Fibre from whole grain foods	Systolic blood pressure	Jenkins et al., 2002[15] Kondo et al., 2017[17]
Total fibre	HbA1c	Chandalia et al., 2000[20] Hollenbeck et al., 1986[21]
Total fibre	Fasting blood glucose	Hollenbeck et al., 1986[21]
Total fibre	Body weight	Chandalia et al., 2000[20]
Total fibre	LDL cholesterol	Chandalia et al., 2000[20] Hollenbeck et al., 1986[21]

HbA1c: glycated haemoglobin, LDL: low-density lipoprotein.

[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.

2.4.2 Selection of prospective cohort studies

The Committee found no SRs (or MAs) of cohort studies, so deemed it worthwhile to search for individual prospective cohort studies into the relationship of dietary fibre intake with risk of long-term health outcomes in people with type 2 diabetes. The main reason was that no evidence for the relationship of dietary fibre with *long-term* health outcomes was available from the selected RCTs, which would be considered highly valuable ancillary evidence. The Committee searched for prospective cohort studies in reviews and in existing external dietary guidelines for diabetes.[22-27] For the individual studies that were retrieved this way, the Committee screened all similar articles and articles citing those studies in PubMed.

Two cohort studies were retrieved via reviews.[28,29] One additional cohort study was retrieved via citing articles in PubMed. Screening of external dietary guidelines for diabetes yielded no additional studies. In total, three prospective cohort studies[30-32] were selected for inclusion (Table 2).
Of those, one study was a pooled analysis of prospective cohort studies[30]; the other two were individual cohort studies.[31,32] The studies examined associations of fibre intake with the risk of all-cause mortality, CVD morbidity and/or CVD mortality. The Committee did not find cohort studies within the pre-specified in- and exclusion criteria for any of the other specified long-term health outcomes and diabetes remission or reversion.

Table 2 Overview of (pooled analyses of) prospective cohort studies selected by the Committee for the evaluation of the relationship between dietary fibre intake and health outcomes, grouped according to the food source of fibre.

Dietary exposure	Health outcome[a]	Pooled analysis (of prospective cohort studies)	Individual prospective cohort studies
Fibre from whole grain foods	All-cause mortality	None	He et al., 2010[31]
Fibre from whole grain foods	Mortality due to CVD	None	He et al., 2010[31]
Total fibre	All-cause mortality	Burger et al., 2012[30]	None
Total fibre	Morbidity or mortality due to CVD	Burger et al., 2012[30]	Tanaka et al., 2013[32]
Total fibre	Morbidity or mortality due to CHD	None	Tanaka et al., 2013[32]
Total fibre	Morbidity or mortality due to stroke	None	Tanaka et al., 2013[32]

CHD: coronary heart disease; CVD: cardiovascular disease.

[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.

2.4.3 Risk of bias assessment

The Cochrane collaboration tool (2011)[33] was used in the MAs by Silva et al.[34], Reynolds et al.[28] and He et al.[35] to assess risk of bias in the included RCTs. The 2011 Cochrane collaboration tool addresses seven specific domains of bias: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other bias. The GRADE assessment[36] was used in the MA by Post et al.[37] GRADE indicates the certainty of the overall body of evidence and is generally used for SRs rather than for individual studies. It incorporates more factors than risk of bias only, such as inconsistency in results (or unexplained heterogeneity) and publication bias.

2.5 Drawing conclusions

A detailed description of the approach used by the Committee to draw conclusions is provided in the background document *Methodology for the evaluation of evidence*.[14] In short, the Committee drew conclusions on (the certainty of) the evidence regarding the effects or associations of higher fibre intake from either whole grain foods or total fibre (i.e. fibre from mixed food sources) with surrogate and long-term health outcomes in people with type 2 diabetes, based on the results of individual RCTs and prospective cohort studies. The Committee took into account the number of studies, number of participants and number of cases that contributed to the evaluation, as well as 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 fibre from whole grain foods

3.1 Evidence from randomised controlled trials

3.1.1. HbA1c

The scientific evidence for effects of increased intake of fibre from whole grain foods on HbA1c in people with type 2 diabetes is described in Table 3.

Table 3 Summary of the effects of increased intake of fibre from whole grain foods on HbA1c in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Jenkins et al., 2002[15]; 12 weeks	Kondo et al., 2017[17]; 8 weeks	Li et al., 2016[18]; 30 days and 1 year	Stevens et al., 1985[19]; 6 weeks
Total number of participants (i/c)	23 (completers)	28 (14/14)	30-d follow-up: 238 (80/79/79) 1-y follow-up: 228 (77/75/76)	25 (13/12; completers)[d]
Study design	Cross-over, wash-out period of 2 months	Parallel	Parallel	Parallel
Fibre dose[a]; diet of intervention (i) and control (c) group	15 g prescribed, 16 g achieved; i: wheat bran added to bread and breakfast cereals, c: white bread and low-fibre breakfast cereals Isocaloric	4 g/d (achieved); i: brown rice, c: white rice Isocaloric	i1: 3 g/d, i2: 6 g/d (achieved[e]); i1: whole grain oats (50 g/d), i2: whole grain oats (100 g/d) c: cereal staple foods Isocaloric	7 g achieved, 13 g prescribed; i: high-fibre (20-30 g/d), low-meat diet plus 50 g/d of oat bran, c: high-fibre (20-30 g/d), low-meat diet
Result	Relative MD in post-intervention values: -2.2%, P=0.263	Absolute mean change (95%CI)[b]: i: -0.2% (-0.5, 0.0) c: -0.1% (-0.3, 0.1) P=0.391	Absolute between-group MD (95%CI)[b,f]: After 30-d follow-up: i1 vs. c: -0.14% (-0.67, 0.39), NS i2 vs. c: -0.10% (-0.63, 0.43), NS After 1-y follow-up: i1 vs. c: -0.48% (-1.02, 0.06), NS i2 vs. c: -0.64% (-1.19, -0.09)	Absolute mean change ± SEM[b]: i: -1.73% ± 0.22 c: -2.08% ± 0.36 P>0.05
Study population	Adults with type 2 diabetes without insulin therapy; BMI[c]: 27 ± 1 kg/m^2; diabetes duration: 1-3 y (n=7), ≥3 y (n=16); diabetes medications: diet alone (n=4), diet and hypoglycaemic agents (n=19); men and (postmenopausal) women; Canada	Adults with type 2 diabetes without insulin therapy and with baseline HbA1c <8.4%; BMI[c]: 24 ± 4 kg/m^2 (i), 25 ± 4 kg/m^2 (c); diabetes duration[c]: 16 ± 10 y (i), 14 ± 7 y (c); diabetes medications: glucose-lowering agents (79% (i), 100% (c)); men and women; Japan	Adults with type 2 diabetes, BMI[c]: 27 ± 3 kg/m^2; diabetes duration[c]: 8 ± 6 y (i1, i2), 6 ± 2 y (c); diabetes medications: none (8%), oral agents only (56%), insulin only (18%), oral agents and insulin (18%); men and women, China	Adults with non-insulin-dependent diabetes (fasting plasma glucose >140 mg/dL); BMI: NR; diabetes duration[c]: 8 ± 3 y (i), 6 ± 2 (c); diabetic medications: NR; men and women; USA

BMI: body mass index; c: control group; CI: confidence interval; d: days; i: intervention group; IQR: interquartile range; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; SEM: standard error of the mean; USA: United States of America; y: years.

[a] Fibre dose represents the difference in fibre intake between the intervention group/phase and control group/phase.
[b] HbA1c usually is expressed in %. This change refers to the absolute change in HbA1c level, i.e. the difference between the post- and pre-intervention HbA1c level and not the relative change in HbA1c.
[c] Mean ± standard deviation.
[d] A total of 60 participants were randomised into four groups, of which 52 completed the study. It is unknown how many were lost to follow-up from the two groups that the Committee considered for its evaluation.
[e] This represents the difference in total fibre intake during the first 30 days of the trial, when complete daily menus were provided.
[f] Adjusted for potential confounding variables including sex, age, drinking, smoking, physical activity level, education level, family history of diabetes, diabetes medications and diabetes duration.

The Committee concluded the following:

Short-term: **There is too little research to draw conclusions regarding the short-term effect of increased intake of fibre from whole grain foods on HbA1c 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 four RCTs, with more than 150 participants, included in the evaluation. This excludes a conclusion with strong evidence, including the conclusion of 'an effect is unlikely'.
2. There is moderate heterogeneity in the direction of the effect. Effect sizes, although small and not statistically significant in any of the four RCTs, point in opposite directions.
3. There is moderate heterogeneity in the size of the effect. Small sample sizes and short follow-up periods in most RCTs and moderate compliance in one RCT may have contributed to the fact that results were not statistically significant (in the short-term). Therefore, the Committee cannot rule out the possibility that an actual effect of increased fibre intake on HbA1c exists.

Long-term: **There is too little research to draw conclusions regarding the long-term effect of increased intake of fibre from whole grain foods on HbA1c 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:
There is one RCT, with more than 150 participants, included in the evaluation. The number of studies is too small to draw any conclusions.

Explanation:

Study characteristics and main effects

Jenkins et al.[15] examined the effect of increased wheat fibre intake on glycaemic control and cardiovascular risk factors in people with (non-insulin-dependent) type 2 diabetes. The RCT had a cross-over design with a wash-out period of two months. During the trial, all participants (n=23) followed a therapeutic lifestyle diet, which is a diet aimed at lowering cholesterol levels.[38] During the intervention phase, participants received high wheat bran breakfast cereals and high wheat bran bread, which provided approximately 19 g of fibre daily. During the control phase, participants received an isocaloric amount of low-fibre breakfast cereals and white bread, which provided approximately 4 g of fibre daily.

The mean of the HbA1c values at weeks 8, 10 and 12 of each phase was used as post-intervention value. The relative difference in post-intervention data of HbA1c between intervention and control was used to examine the effect of increased fibre intake. Post-intervention HbA1c values were on average 2.2% lower (relatively) after the intervention

phase compared to the control phase but this effect was not statistically significant (P=0.263). Of note, HbA1c levels were already slightly lower at the start of the intervention phase compared to the control phase, and during both phases a slight increase in HbA1c was observed: from 7.0 ± 0.2% (mean ± standard deviation (SD); at baseline) to 7.2 ± 0.2% (after 8-12 weeks) during the intervention phase and from 7.3 ± 0.3% to 7.4 ± 0.3% during the control phase (statistical significance not reported). This means that while the post-intervention HbA1c values tend to show a reducing effect in favour of the intervention, the change values tend to show the opposite.

Kondo et al.[17] examined the effects of a fibre-rich diet on endothelial function (primary outcome) and HbA1c, fasting blood glucose, body weight, cholesterol and blood pressure (secondary outcomes) in people with type 2 diabetes. The RCT had a parallel design and included participants that did not receive insulin therapy and had a baseline HbA1c <8.4%. During the trial, all participants (n=28) followed a standard diabetes diet, comprised of 28-30 kcal per kilogram of ideal body weight (15 per cent of energy (E%) from protein, 25 E% fat, 60 E% carbo-hydrate). The intervention group received packages of brown rice (blended with barley and amaranth to improve viscosity and flavour) providing 4.3 g of fibre each. The control group received packages with an isocaloric amount of white rice providing 0.5 g of fibre each. Both groups were instructed to use one rice package as staple food for 10 out of 21 meals per week.

After eight weeks, mean (absolute) HbA1c had changed by -0.2% (95% confidence interval (CI): -0.5, 0.0) and -0.1% (-0.3, 0.1) in the intervention group and control group, respectively, but this difference in change between the groups was not statistically significant (P=0.391).

Li et al.[18] examined the effect of whole grain oat intake on weight management, blood glucose control and lipid profile in overweight (body mass index (BMI) >24 kg/m^2) people with type 2 diabetes. The RCT had a parallel design with three arms and a follow-up of 30 days and 1 year. Participants resided in a hotel during the first 30 days of the trial and had meals together. All participants (n=238) received a low-fat, high-fibre diet, comprised of 2275 and 1890 kcal for men and women, respectively (18 E% protein, 22 E% fat, 60 E% carbohydrate, 30 g of fibre). A maximum of 10% extra energy was allowed for individual needs. In addition, all participants got nutritional education from dieticians. Compared to the control group, the intervention groups consumed porridge made of 50 g/d (i1) or 100 g/d (i2) of whole grain oats (8.7 g of fibre per 100 g of oats; about 60% beta-glucan) instead of an isocaloric amount of cereal staple foods. After the 30-day hotel stay, participants were asked to continue their intervention at home for 1 year. Provision of whole grain oats and nutritional education continued throughout this period.

After 30 days, mean (absolute) HbA1c had decreased 0.14% (95%CI -0.39, 0.67) and 0.10% (-0.43, 0.63) more in intervention groups 1 and 2, respectively, compared to the control group, after adjustment for potential confounding variables. These differences were not statistically significant. After 1 year, a (borderline) statistically significant greater decrease in (absolute) HbA1c of 0.48% (-0.06, 1.02) and 0.64% (0.09, 1.19) in intervention groups 1 and 2, respectively, compared to the control group was observed after adjustment for potential confounding variables.
The greater and statistically significant decrease in HbA1c after 1 year compared to 30 days can be most likely explained by the fact that HbA1c reflects blood glucose levels over a period of 2 to 3 months, so that 30 days were too few to detect changes in HbA1c.

Stevens et al.[19] examined the effect of increased fibre intake on parameters of diabetes control and serum lipids in people with non-insulin-dependent diabetes mellitus (NIDDM). The RCT had a parallel design with four arms, of which two arms were relevant for the Committee's evaluation. One group (n=12), which is here considered the control group, was advised a calorie-restricted diet (and advised to lose 0.5-1.0 kg of body weight per week). Participants in the control group were additionally advised to consume 3-4 oz of meat and 20-30 g of fibre daily, and to limit the intake of simple sugars, saturated fat and cholesterol. The intervention group (n=13) received the same dietary advice as the control group with the only difference being that the intervention group was additionally advised to consume 50 g of oat bran daily (oat bran was provided), which contains 13 g of fibre.
After six weeks, (absolute) HbA1c had decreased less in the intervention group (mean change ± standard error of the mean (SEM): -1.73 ± 0.22%) compared to the control group (-2.08 ± 0.36%). These changes between the groups were not statistically significant. Of note, mean (± SEM) HbA1c was very high in both groups at baseline: 14 ± 1%.

Risk of bias

Risk of bias in the RCT by Jenkins et al. was assessed with the Cochrane collaboration tool (2011) in the MA by Silva et al.[34] The risk of attrition bias (missing outcome data) was scored as high. Of the 65 participants randomised, only 23 participants completed both trial phases. Fifteen participants withdrew before the start of the first phase, 14 participants withdrew during the first phase and seven participants withdrew thereafter (control: n=13, intervention: n=8) and six participants withdrew during the second phase. Reasons for withdrawal may be related to the intervention, such as intervention-related diarrhoea, poor glycaemic control and poor compliance. Whether allocation was concealed and outcome assessors were blinded is unclear, which may increase the risk of selection bias and detection bias, respectively. Risk of bias in the RCT by Kondo et al. was assessed with the Cochrane collaboration tool (2011) in the SR by Reynolds et al.[28] The overall risk of bias was scored as low. Risk of bias in the RCT by Li et al. was also assessed in the SR by Reynolds et al.[28]

Risk of selective reporting was scored as high. Whether sequence generation was random, allocation was concealed and participants were blinded is unclear, which may increase the risk of selection bias and performance bias, respectively. Risk of bias in the RCT by Stevens et al. was assessed in the MA by He et al.[35] Risk of selective reporting was scored as high. Whether sequence generation was random, allocation was concealed, and participants, personnel and outcome assessors were blinded is unclear, which may increase the risk of selection bias, performance bias and detection bias, respectively. Due to the nature of the intervention, the Committee considers it unlikely that participants were blinded.

Funding

The funding sources of the evaluated studies and conflicts of interests of the authors are presented in **Annex C**. The foods used in the study by Jenkins et al. were donated by food companies. Whether or not the funders were involved in the study was not reported and, therefore, the impact on the study findings remains unclear. For the other studies, no notable funding sources or conflicts of interests were reported.

Compliance

In the RCT by Jenkins et al., compliance was assessed by participant's diet histories and by weighing of returned unconsumed supplements. Authors reported that the compliance was good for both the test products and control products (97 ± 2% and 96 ± 2% of prescribed energy, respectively). In the RCT by Kondo et al., compliance with the provided rice packages was not reported. However, participants completed a 3-day dietary record to estimate total food intake including total fibre intake. During the intervention, total dietary fibre intake increased statistically significantly more in the intervention group than in the control group (mean difference: 6.8 g/d), suggesting that compliance was good. Compliance in the RCT by Li et al. was not reported. In the RCT by Stevens et al., compliance was moderate. The authors reported that the compliance to the oat bran was generally good but that participants tended to substitute the oat bran for other high-fibre foods. Therefore, the increase in fibre intake was less than anticipated. This may account for not observing an effect on HbA1c.

Summary

The Committee included four RCTs in the evaluation of the short-term effect of increased intake of fibre from whole grain foods on HbA1c in people with type 2 diabetes. All four RCTs, with a maximum duration of 12 weeks, showed no statistically significant effect. The short intervention duration and relatively small sample sizes in most studies and moderate compliance in one study may hinder the observation of an effect of increased fibre intake on HbA1c. The single RCT included in the long-term evaluation showed a statistically significant beneficial effect of higher fibre intake on HbA1c after 1 year.

3.1.2 Fasting blood glucose

The scientific evidence for effects of increased intake of fibre from whole grain foods on fasting blood glucose in people with type 2 diabetes is described in Table 4.

Table 4 Summary of the effects of increased intake of fibre from whole grain foods on fasting blood glucose in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Jenkins et al., 2002[15]; 12 weeks	Karlström et al., 1984[16]; 3 weeks	Kondo et al., 2017[17]; 8 weeks	Li et al., 2016[18]; 30 days and 1 year	Stevens et al., 1985[19]; 6 weeks
Total number of participants	23 (completers)	14	28 (14/14)	30-d follow-up: 238 (80/79/79) 1-y follow-up: 228 (77/75/76)	25 (13/12; completers)[e]
Study design	Cross-over, wash-out period of 2 months	Cross-over, no wash-out period	Parallel	Parallel	Parallel
Fibre dose[a]; diet of intervention (i) and control (c) group	15 g prescribed, 16 g achieved; i: wheat bran added to bread and breakfast cereals, c: white bread and low-fibre breakfast cereals Isocaloric	23 g/1600 kcal (prescribed); i: high-fibre diet using fibre-rich rye crispbread and wholemeal bread, c: moderate-fibre diet using wheat crispbread and white wheat-bread Isocaloric	4 g/d (achieved); i: brown rice, c: white rice Isocaloric	i1: 3 g/d, i2: 6 g/d (achieved[c]); i1: whole grain oats (50 g/d), i2: whole grain oats (100 g/d) c: cereal staple foods Isocaloric	7 g achieved, 13 g prescribed; i: high-fibre (20-30 g/d), low-meat diet plus 50 g/d of oat bran, c: high-fibre (20-30 g/d), low-meat diet
Result	Relative MD in post-intervention values: -3.7%, P=0.154	Post-intervention values (mean ± SEM): i: 9.5 mmol/L ± 0.6 c: 10.1 mmol/L ± 0.6 P<0.05	Between-group MD (95%CI): -0.38 mmol/L (-1.02, 0.25), *P*=0.228	Between-group MD (95%CI)[d]: After 30-d follow-up: i1 vs. c: 0.04 mmol/L (-0.81, 0.89), NS i2 vs. c: -0.43 mmol/L (-1.28, 0.42), NS After 1-y follow-up: i1 vs. c: 0.03 mmol/L (-0.76, 0.82), NS i2 vs. c: -0.22 mmol/L (-1.02, 0.58), NS	Mean change ± SEM: i: -40.0 ± 11.0 mg/dL (-2.2 ± 0.6 mmol/L) c: -58.2 ± 12.3 mg/dL (-3.2 ± 0.7 mmol/L) P>0.05

Study; study duration	Jenkins et al., 2002[15]; 12 weeks	Karlström et al., 1984[16]; 3 weeks	Kondo et al., 2017[17]; 8 weeks	Li et al., 2016[18]; 30 days and 1 year	Stevens et al., 1985[19]; 6 weeks
Study population	Adults with type 2 diabetes without insulin therapy; BMI[b]: 27 ± 1 kg/m^2; diabetes duration: 1-3 y (n=7), ≥3 y (n=16); diabetes medications: diet alone (n=4), diet and hypoglycaemic agents (n=19); men and (postmenopausal) women; Canada	Adults with non-insulin-dependent type 2 diabetes; BMI[b]: 25 ± 1 kg/m^2; diabetes duration 1-5 y (n=4), ≥5 y (n=10); diabetes medications: diet alone (n=3), diet and oral antidiabetic drugs (n=11); men and women; Europe	Adults with type 2 diabetes without insulin therapy and with baseline HbA1c <8.4%; BMI[b]: 24 ± 4 kg/m^2 (i), 25 ± 4 kg/m^2 (c); diabetes duration[b]: 16 ± 10 y (i), 14 ± 7 y (c); diabetes medications: glucose-lowering agents (79% (i), 100% (c)); men and women; Japan	Adults with type 2 diabetes, BMI[b]: 27 ± 3 kg/m^2; diabetes duration[b]: 8 ± 6 y (i1, i2), 6 ± 2 y (c); diabetes medications: none (8%), oral agents only (56%), insulin only (18%), oral agents and insulin (18%); men and women, China	Adults with non-insulin-dependent diabetes (fasting plasma glucose >140 mg/dL); BMI: NR; diabetes durationb: 8 ± 3 y (i), 6 ± 2 (c); diabetic medications: NR; men and women; USA

BMI: body mass index; c: control group; CI: confidence interval; d: days; i: intervention group; IQR: interquartile range; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; SEM: standard error of the mean; USA: United States of America; y: years.

[a] Fibre dose represents the difference in fibre intake between the intervention group/phase and control group/phase.
[b] Mean ± standard deviation.
[c] This represents the difference in total fibre intake during the first 30 days of the trial, when complete daily menus were provided.
[d] Adjusted for potential confounding variables including sex, age, drinking, smoking, physical activity level, education level, family history of diabetes, diabetes medications and diabetes duration.
[e] A total of 60 participants were randomised of which 52 completed the study. Participants were randomised into four groups and it is unknown how many were lost to follow-up from the two groups that the Committee considered for its evaluation.

The Committee concluded the following:

***Short-term:* There is inconclusive evidence regarding the effect of increased intake of fibre from whole grain foods on fasting blood glucose within 3 to 12 weeks 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 five RCTs, with more than 150 participants, included in the evaluation. This is the first step required to mark the evidence as strong. However, there were other considerations that lead to the conclusion of ‘inconclusive evidence’, as described below.``
2. There is moderate heterogeneity in the direction of the effects. A significant beneficial effect of increased fibre intake was observed in one small RCT with a follow-up of three weeks. In one RCT, the effect estimate points in the opposite direction (unfavourable effect), although the effect was not statistically significant. The other three RCTs also showed no statistically significant effect.
3. The tendency towards an unfavourable effect of increased fibre intake shown in one RCT may be due to moderate compliance with the intervention. In one RCT the drop-out rate was very high, which may have hindered the observation of a statistically significant effect. Furthermore, there is moderate heterogeneity in the size of the effects. The Committee noted there were differences in fibre dose and duration

of the studies, which may have contributed to differences in results between studies.

Long-term: **There is too little research to draw conclusions regarding the long-term effect of increased intake of fibre from whole grain foods on fasting blood glucose 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:

There is one RCT, with more than 150 participants, included in the evaluation. The number of studies is too small to draw any conclusions.

Explanation:

Study characteristics and main effects

Jenkins et al.[15] examined the effect of increased wheat fibre intake on glycaemic control and cardiovascular risk factors in (non-insulin-dependent) people with type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a cross-over design and participants (n=23) received high-fibre cereal products providing 19 g/d of fibre in the intervention phase and low-fibre cereal products providing 4 g/d of fibre in the control phase.

After eight to 12 weeks, post-intervention fasting blood glucose levels were on average 3.7% lower after the intervention phase compared to the control phase but this effect was not statistically significant (P=0.154). Of note, during both the intervention phase and the control phase a slight increase in fasting blood glucose was observed: from 7.3 ± 0.3 mmol/L to 7.5 ± 0.3 mmol/L during the intervention phase and from 7.4 ± 0.4 mmol/L to 7.9 ± 0.4 mmol/L during the control phase (statistical significance not reported).

Karlström et al.[16] examined the effects of increased cereal fibre intake on metabolic control in people with type 2 diabetes. The RCT had a cross-over design without a wash-out period. Participants (n=14) received individualized weekly menus containing approximately 19 g of fibre per 1600 kcal in the control phase and 42 g of fibre per 1600 kcal in the intervention phase. The difference in fibre content between the diets was accomplished through different types of cereal. In the control phase, participants received wheat crispbread and soft bread made of white wheat flour. In the intervention phase, participants received rye crispbread and soft bread made of wheat flour, rye flour, wheat bran, crushed wheat grain and wholemeal rye. Diets were isocaloric and similar in macronutrient composition.

Fasting blood glucose was approximately 0.6 mmol/L lower after the 3-week intervention phase (mean ± SEM: 9.5 ± 0.6 mmol/L) compared to the 3-week control phase (10.1 ± 0.6 mmol/L); this difference was statistically significant (P<0.05). Baseline values of fasting blood glucose were not different between phases and fasting blood glucose levels

decreased during both phases, suggesting a reducing effect of dietary fibre on fasting blood glucose. The fibre dose in this study was substantially greater compared to the other RCTs in this evaluation. The study duration, however, was substantially shorter compared to the other RCTs.

Kondo et al.[17] examined the effects of a fibre-rich diet on multiple cardio-vascular risk factors in people with (non-insulin-dependent) type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design. The intervention group (n=14) was instructed to consume brown rice (4.3 g of fibre per provided package of rice) and the control group (n=14) was instructed to consume an isocaloric amount of white rice (0.5 g of fibre per package) for ten out of 21 meals per week.

After eight weeks, mean fasting blood glucose had decreased 0.38 mmol/L (95%CI: -0.25, 1.02) more in the intervention group compared to the control group but this difference was not statistically significant (P=0.228).

Li et al.[18] examined the effect of whole grain oat intake on weight management, blood glucose control and lipid profile in overweight people with type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design with three arms and a follow-up of 30 days and 1 year. Intervention groups 1 (n=80) and 2 (n=79) were instructed to consume 50 g/d or 100 g/d of whole grain oats, respectively, instead of an isocaloric amount of cereal staple foods (control group, n=79).

After 30 days, fasting blood glucose had decreased on average 0.43 mmol/L (95%CI: -0.42, 1.28) more in intervention group 2 compared to the control group, although the difference was not statistically significant. No difference in change was observed between intervention group 1 and the control group. Similar non-statistically significant results were observed after 1 year of follow-up; fasting blood glucose decreased 0.22 mmol/L (-0.58, 1.02) more in intervention group 2 compared to the control group, but no difference in change was observed between intervention group 1 and the control group.

Stevens et al.[19] examined the effect of increased fibre intake on parameters of diabetes control and serum lipids in people with non-insulin-dependent diabetes mellitus (NIDDM), as previously described in section 3.1.1. In short, the RCT had a parallel design and both groups were advised an energy-restricted diet. The intervention group (n=13) was additionally advised to consume 50 g of oat bran daily (13 g of dietary fibre), whereas the control group was not. The study was likely not isocaloric.

After six weeks, fasting blood glucose had decreased in both groups but the decrease was less in the intervention group (mean change ± SEM:

-2.2 ± 0.6 mmol/L) compared to the control group (-3.2 ± 0.7 mmol/L). These changes between the groups were not statistically significantly different. The authors did not report an explanation for this. Interestingly, the intervention group lost more body weight than the control group but this appears not to be related to the fasting blood glucose levels.

Risk of bias

In the RCT by Jenkins et al., the risk of attrition bias (due to a high drop-out rate of approximately 60%) was scored as high. Whether allocation was concealed and outcome assessors were blinded is unclear. In the RCT by Kondo et al., the overall risk of bias was scored as low. Risk of bias in the RCT by Karlström et al. was judged in the MA by Post et al.[37] using the GRADE assessment. The study quality was scored as high. In the RCT by Li et al., risk of selective reporting was scored as high but the authors did not motivate their judgment. Whether sequence generation was random, allocation was concealed and participants were blinded is unclear. In the RCT by Stevens et al., risk of selective reporting was scored as high but the authors' judgment was not motivated. Whether sequence generation was random, allocation was concealed, and participants, personnel and outcome assessors were blinded is unclear. Due to the nature of the intervention, it is unlikely that participants were blinded.

Funding

The foods used in the studies by Jenkins et al. and by Karlström et al. were donated by food companies (**Annex C**). Whether or not the funders were involved in the study was not reported and, therefore, the impact on the study findings remains unclear. For the other studies, no notable funding sources or conflicts of interests were reported.

Compliance

Compliance was good in the RCTs by Jenkins et al. and Kondo et al. The moderate compliance in the RCT by Stevens et al. probably resulted in a lesser increase in fibre intake than anticipated, which may account for not observing an effect on fasting blood glucose. Compliance was not reported in the RCTs by Karlström et al. and Li et al.

Summary

The Committee included five RCTs in the evaluation of the short-term effect of increased intake of fibre from whole grain foods on fasting blood glucose in people with type 2 diabetes. One RCT showed a statistically significant beneficial effect of higher fibre intake on fasting blood glucose within 3 weeks of follow-up, whereas the other four RCTs (with a duration of 6 to 12 weeks) showed no effect. There were some concerns with regard to the risk of bias due to a high drop-out rate and moderate compliance with the intervention in some studies. The Committee noted there were differences in fibre dose and duration of the studies, which

may have contributed to differences in results between studies. The single RCT included in the long-term evaluation showed no effect of increased intake of fibre from whole grain foods on fasting blood glucose within 1 year.

3.1.3 Body weight

The scientific evidence for effects of increased intake of fibre from whole grain foods on body weight in people with type 2 diabetes is described in Table 5.

Table 5 Summary of the effects of increased intake of fibre from whole grain foods on body weight in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Jenkins et al., 2002[15]; 12 weeks	Kondo et al., 2017[17]; 8 weeks	Li et al., 2016[18]; 30 days and 1 year	Stevens et al., 1985[19]; 6 weeks
Total number of participants (i/c)	23 (completers)	28 (14/14)	30-d follow-up: 238 (80/79/79) 1-y follow-up: 228 (77/75/76)	25 (13/12; completers)[c]
Study design	Cross-over, wash-out period of 2 months	Parallel	Parallel	Parallel
Fibre dose[a]; diet of intervention (i) and control (c) group	15 g prescribed, 16 g achieved; i: wheat bran added to bread and breakfast cereals, c: white bread and low-fibre breakfast cereals Isocaloric	4 g/d (achieved); i: brown rice, c: white rice Isocaloric	i1: 3 g/d, i2: 6 g/d (achieved[d]); i1: whole grain oats (50 g/d), i2: whole grain oats (100 g/d) c: cereal staple foods Isocaloric	7 g achieved, 13 g prescribed; i: high-fibre (20-30 g/d), low-meat diet plus 50 g/d of oat bran, c: high-fibre (20-30 g/d), low-meat diet
Result	Relative MD in post-intervention values: 0.0%, P=0.915	Mean change (95%CI): i: -0.6 kg (-1.3, 0.1) c: -0.3 kg (-0.7, 0.1) P=0.468	Between-group MD (95%CI)[e]: After 30-d follow-up: i1 vs. c: -0.47 kg (-1.89, 0.96), NS i2 vs. c: -0.54 kg (-1.97, 0.89), NS After 1-y follow-up: i1 vs. c: -0.36 kg (-1.10, 0.38), NS i2 vs. c: -0.89 kg (-1.56, -0.22)	Mean change ± SEM: i: -2.28 kg ± 0.51 c: -0.66 kg ± 0.37 P<0.05
Study population	Adults with type 2 diabetes without insulin therapy; BMI[b]: 27 ± 1 kg/m^2; diabetes duration: 1-3 y (n=7), ≥3 y (n=16); diabetes medications: diet alone (n=4), diet and hypoglycaemic agents (n=19); men and (postmenopausal) women; Canada	Adults with type 2 diabetes without insulin therapy and with baseline HbA1c <8.4%; BMI[b]: 24 ± 4 kg/m^2 (i), 25 ± 4 kg/m^2 (c); diabetes duration[b]: 16 ± 10 y (i), 14 ± 7 y (c); diabetes medications: glucose-lowering agents (79% (i), 100% (c)); men and women; Japan	Adults with type 2 diabetes, BMI[b]: 27 ± 3 kg/m^2; diabetes duration: 8 ± 6 y (i1, i2), 6 ± 2 y (c); diabetes medications: none (8%), oral agents only (56%), insulin only (18%), oral agents and insulin (18%); men and women; China	Adults with non-insulin-dependent diabetes (fasting plasma glucose >140 mg/dL); BMI: NR; diabetes duration[b]: 8 ± 3 y (i), 6 ± 2 (c); diabetic medications: NR; men and women; USA

BMI: body mass index; c: control group; CI: confidence interval; d: days; i: intervention group; IQR: interquartile range; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; SEM: standard error of the mean; USA: United States of America; y: years.

[a] Mean difference in adjusted change. Change in HbA1c from baseline was adjusted for potential confounding variables (sex, age, drinking, smoking, physical activity level, education level, BMI, family history of diabetes, medications and duration of diabetes) in the analysis of covariance model.

[b] Mean ± standard deviation.

[c] A total of 60 participants were randomised of which 52 completed the study. Participants were randomised into four groups and it is unknown how many were lost to follow-up from the two groups that the Committee considered for evaluation.

[d] This represents the difference in total fibre intake during the first 30 days of the trial, when complete daily menus were provided.

[e] Adjusted for potential confounding variables including sex, age, drinking, smoking, physical activity level, education level, family history of diabetes, diabetes medications and diabetes duration.

The Committee concluded the following:

Short-term: **There is too little research to draw conclusions regarding the short-term effect of increased intake of fibre from whole grain foods on body weight 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 four RCTs, with more than 150 participants, included in the evaluation. This excludes a conclusion with strong evidence, including the conclusion of ‘an effect is unlikely’ or ‘evidence is inconclusive’.
2. There is no obvious heterogeneity in the direction of the effect.
3. There is moderate heterogeneity in the size of the effects. One RCT showed a statistically significantly beneficial (reducing) effect of increased fibre intake on body weight within 6 weeks, whereas the other three RCTs showed no statistically significant effect within 30 days to 12 weeks. There are some concerns regarding compliance with the intervention in the study showing an effect. Furthermore, the Committee noted there were differences in intervention type and duration of the studies, which may have contributed to differences in results between studies.

Long-term: **There is too little research to draw conclusions regarding the long-term effect of increased intake of fibre from whole grain foods on body weight 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:

There is one RCT, with more than 150 participants, included in the evaluation. The number of studies is too small to draw any conclusions.

Explanation:

Study characteristics and main effects

Jenkins et al.[15] examined the effect of increased wheat fibre intake on glycaemic control and cardiovascular risk factors in (non-insulin-dependent) people with type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a cross-over design and participants (n=23) received high-fibre cereal products providing 19 g/d of fibre in the intervention phase and low-fibre cereal products providing 4 g/d of fibre in the control phase.

After eight to 12 weeks, body weight had not changed in either group (at both baseline and follow-up and in both groups mean body weight was 74 ± 3 kg), so no effect of fibre intake on body weight was observed (P=0.915).

Kondo et al.[17] examined the effects of a fibre-rich diet on multiple cardiovascular risk factors in people with (non-insulin-dependent) type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design. The intervention group (n=14) was instructed to consume

brown rice (4.3 g of fibre per provided package of rice) and the control group (n=14) was instructed to consume an isocaloric amount of white rice (0.5 g of fibre per package) for ten out of 21 meals per week.

After eight weeks, mean body weight had changed by -0.6 kg (95%CI: -1.3, 0.1) and -0.3 kg (-0.7, 0.1) in the intervention group and control group, respectively, but this difference in change between the groups was not statistically significant (P=0.468).

Li et al.[18] examined the effect of whole grain oat intake on weight management, blood glucose control and lipid profile in overweight people with type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design with three arms and a follow-up of 30 days and 1 year. Intervention groups 1 (n=80) and 2 (n=79) were instructed to consume 50 g/d or 100 g/d of whole grain oats, respectively, instead of an isocaloric amount of cereal staple foods (control group, n=79).

After 30 days, body weight had decreased 0.47 kg (95%CI -0.96, 1.89) and 0.54 kg (-0.89, 1.97) more in intervention groups 1 and 2, respectively, compared to the control group, but these differences were not statistically significant. After 1 year of follow-up, a non-statistically significant greater decrease of 0.36 kg (-0.38, 1.10) was observed in intervention group 1 compared to the control group. However, a statistically significant greater decrease in body weight of 0.89 kg (0.22, 1.56) was observed in intervention group 2 compared to the control group.

Stevens et al.[19] examined the effect of increased fibre intake on parameters of diabetes control and serum lipids in people with non-insulin-dependent diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design and both groups were advised an energy-restricted diet. The intervention group (n=13) was additionally advised to consume 50 g of oat bran daily (13 g of dietary fibre), whereas the control group was not. The study was likely not isocaloric.

After six weeks, body weight had decreased statistically significantly more in the intervention group (mean change ± SEM: -2.28 kg ± 0.51) compared to the control group (-0.66 kg ± 0.37). The Committee presumes that the greater decrease in body weight in the intervention group might be attributable to the satiating effect of fibre thereby reducing energy intake.

Risk of bias

In the RCT by Jenkins et al., the risk of attrition bias (due to a high drop-out rate of approximately 60%) was scored as high. Whether allocation was concealed and outcome assessors were blinded is unclear. In the RCT by Kondo et al., the overall risk of bias was scored as low. In the RCT by Li et al., risk of selective reporting was scored as high but the

authors did not motivate their judgment. Whether sequence generation was random, allocation was concealed and participants were blinded is unclear. In the RCT by Stevens et al., risk of selective reporting was scored as high but the authors' judgment was not motivated. Whether sequence generation was random, allocation was concealed, and participants, personnel and outcome assessors were blinded is unclear. Due to the nature of the intervention, it is unlikely that participants were blinded.

Funding

The foods used in the study by Jenkins et al. were donated by food companies (**Annex C**). Whether or not the funders were involved in the study was not reported and, therefore, the impact on the study findings remains unclear. For the other studies, no notable funding sources or conflicts of interests were reported.

Compliance

Compliance was good in the RCTs by Jenkins et al. and Kondo et al., and moderate in the RCT by Stevens et al. Although the intervention in the RCT by Stevens et al. was not isocaloric (i.e. the prescribed energy content was likely higher in the intervention compared to the control group), the higher intake of fibre in the intervention group might have induced greater satiety thereby reducing energy intake and resulting in more weight loss. Compliance was not reported in the RCT by Li et al.

Summary

The Committee included four RCTs in the evaluation of the short-term effect of increased intake of fibre from whole grain foods on body weight in people with type 2 diabetes. One RCT showed a statistically significant beneficial (reducing) effect of increased fibre intake on body weight after 6 weeks of follow-up, whereas the other three RCTs (with a duration of 30 days to 12 weeks) showed no effect. In the RCT that showed a beneficial effect, the intervention was likely not isocaloric, compliance was moderate and energy intake was not reported. In this RCT, it is possible that the higher intake of fibre in the intervention group might have induced satiety thereby reducing energy intake. The Committee furthermore noted there were differences in type of intervention and duration of the studies, which may have contributed to differences in results between studies. The single RCT included in the long-term evaluation showed a statistically significant beneficial (reducing) effect of increased fibre intake on body weight within 1 year.

3.1.4 LDL cholesterol

The scientific evidence for effects of increased intake of fibre from whole grain foods on LDL cholesterol in people with type 2 diabetes is described in Table 6.

Table 6 Summary of the effects of increased intake of fibre from whole grain foods on LDL cholesterol in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Jenkins et al., 2002[15]; 12 weeks	Karlström et al., 1984[16]; 3 weeks	Kondo et al., 2017[17]; 8 weeks	Li et al., 2016[18]; 30 days and 1 year
Total number of participants (i/c)	23 (completers)	14	28 (14/14)	30-d follow-up: 238 (80/79/79) 1-y follow-up: 228 (77/75/76)
Study design	Cross-over, wash-out period of 2 months	Cross-over, no wash-out period	Parallel	Parallel
Fibre dose[a]; diet of intervention (i) and control (c) group	15 g prescribed, 16 g achieved; i: wheat bran added to bread and breakfast cereals, c: white bread and low-fibre breakfast cereals Isocaloric	23 g/1600 kcal (prescribed); i: high-fibre diet using fibre-rich rye crispbread and wholemeal bread, c: moderate-fibre diet using wheat crispbread and white wheat-bread Isocaloric	4 g/d (achieved); i: brown rice, c: white rice Isocaloric	i1: 3 g/d, i2: 6 g/d (achieved[c]); i1: whole grain oats (50 g/d), i2: whole grain oats (100 g/d) c: cereal staple foods Isocaloric
Result	Relative MD in post-intervention values: +0.6%, P=0.798	Post-intervention values (mean ± SEM): i: 3.49 mmol/L ± 0.20 c: 3.68 mmol/L ± 0.20 P<0.05	Between-group MD (95%CI): -0.13 mmol/L (-0.5, 0.2), P=0.431	Between-group MD (95%CI)[d]: After 30-d follow-up: i1 vs. c: -0.10 mmol/L (-0.28, 0.08) i2 vs. c: -0.22 mmol/L (-0.41, -0.03) After 1-y follow-up: i1 vs. c: -0.27 mmol/L (-0.49, -0.05) i2 vs. c: -0.37 mmol/L (-0.59, -0.15)
Study population	Adults with type 2 diabetes without insulin therapy; BMI[b]: 27 ± 1 kg/m^2; diabetes duration: 1-3 y (n=7), ≥3 y (n=16); diabetes medications: diet alone (n=4), diet and hypoglycaemic agents (n=19); men and (postmenopausal) women; Canada	Adults with non-insulin-dependent type 2 diabetes; BMI[b]: 25 ± 1 kg/m^2; diabetes duration 1-5 y (n=4), ≥5 y (n=10); diabetes medications: diet alone (n=3), diet and oral antidiabetic drugs (n=11); men and women; Europe	Adults with type 2 diabetes without insulin therapy and with baseline HbA1c <8.4%; BMI[b]: 24 ± 4 kg/m^2 (i), 25 ± 4 kg/m^2 (c); diabetes duration[b]: 16 ± 10 y (i), 14 ± 7 y (c); diabetes medications: glucose-lowering agents (79% (i), 100% (c)); men and women; Japan	Adults with type 2 diabetes, BMI[b]: 27 ± 3 kg/m^2; diabetes duration: 8 ± 6 y (i1, i2), 6 ± 2 y (c); diabetes medications: none (8%), oral agents only (56%), insulin only (18%), oral agents and insulin (18%); men and women; China

BMI: body mass index; c: control group; CI: confidence interval; d: days; i: intervention group; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; SEM: standard error of the mean; y: years.

[a] Fibre dose represents the difference in fibre intake between the intervention group and the control group.

[b] Mean ± standard deviation.

[c] This represents the difference in total fibre intake during the first 30 days of the trial, when complete daily menus were provided.

[d] Adjusted for potential confounding variables including sex, age, drinking, smoking, physical activity level, education level, family history of diabetes, diabetes medications and diabetes duration.

The Committee concluded the following:

Short-term: **There is too little research to draw conclusions regarding the short-term effect of higher intake of fibre from whole grain foods on LDL cholesterol 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 four RCTs, with more than 150 participants, included in the evaluation. This excludes a conclusion with strong evidence, including the conclusion of 'an effect is unlikely' or 'evidence is inconclusive'.
2. There is moderate heterogeneity in the direction of the effect. Two RCTs showed a statistically significant beneficial (reducing) effect of increased fibre intake on LDL cholesterol after 3 weeks to 30 days of follow-up, whereas the other two RCTs showed no statistically significant effect after 8 to 12 weeks. One of those latter RCTs points in the direction of a non-statistically significant unfavourable (increasing) effect.
3. There is moderate heterogeneity in the size of the effects, especially given the differences in study duration. The study that pointed towards an unfavourable effect of increased fibre intake had a high risk of bias and is therefore given less weight. Compliance with the intervention was generally good in two RCTs and is unknown for the other two RCTs. Differences in intervention type might (partly) account for the different effect sizes observed.

Long-term: **There is too little research to draw conclusions regarding the long-term effect of higher intake of fibre from whole grain foods on LDL cholesterol 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:

There is one RCT, with more than 150 participants, included in the evaluation. The number of studies is too small to draw any conclusions.

Explanation:

Study characteristics and main effects

Jenkins et al.[15] examined the effect of increased wheat fibre intake on glycaemic control and cardiovascular risk factors in (non-insulin-dependent) people with type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a cross-over design and participants (n=23) received high-fibre cereal products providing 19 g/d of fibre in the intervention phase and low-fibre cereal products providing 4 g/d of fibre in the control phase.

After eight to 12 weeks, post-intervention LDL cholesterol levels were on average 0.6% higher in the intervention group compared to the control group, but this effect was not statistically significant (P=0.798). Of note, LDL cholesterol was slightly lower at baseline in the intervention group compared to the control group and LDL cholesterol increased in the intervention group (from 2.93 ± 0.18 mmol/L to 3.00 ± 0.15 mmol/L)

whereas it did not change in the control group (2.99 mmol/L at both baseline and post-intervention). This means that the difference in *change* in LDL cholesterol is greater than 0.6%.

Karlström et al.[16] examined the effects of increased cereal fibre intake on metabolic control in people with (non-insulin-dependent) type 2 diabetes, as previously described in section 3.1.2. In short, the RCT had a cross-over design without a wash-out period. Participants (n=14) received bread made out of whole grain wheat and rye (42 g of fibre/1600 kcal) during the intervention phase and bread made of white wheat flour (19 g of fibre/1600 kcal) during the control phase. Diets were isocaloric and similar in macronutrient composition.

LDL cholesterol was statistically significantly lower after the 3-week intervention phase (mean ± SEM: 3.49 ± 0.20 mmol/L) compared to the 3-week control phase (3.68 ± 0.20 mmol/L). Baseline values of LDL cholesterol were not reported.

Kondo et al.[17] examined the effects of a fibre-rich diet on multiple cardiovascular risk factors in people with (non-insulin-dependent) type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design. The intervention group (n=14) was instructed to consume brown rice (4.3 g of fibre per provided package of rice) and the control group (n=14) was instructed to consume an isocaloric amount of white rice (0.5 g of fibre per package) for ten out of 21 meals per week.

After eight weeks, mean LDL cholesterol had decreased 0.13 mmol/L (95%CI: -0.2, 0.5) more in the intervention group compared to the control group but this difference was not statistically significant (P=0.431).

Li et al.[18] examined the effect of whole grain oat intake on weight management, blood glucose control and lipid profile in overweight people with type 2 diabetes, as previously described in section 3.1.1. In short, the RCT had a parallel design with three arms and a follow-up of 30 days and 1 year. Intervention groups 1 (n=80) and 2 (n=79) were instructed to consume 50 g/d or 100 g/d of whole grain oats, respectively, instead of an isocaloric amount of cereal staple foods (control group, n=79).

After 30 days, a (borderline) statistically significant greater decrease in LDL cholesterol of 0.10 mmol/L (95%CI -0.08, 0.28) and 0.22 mmol/L (0.03, 0.41) in intervention groups 1 and 2, respectively, compared to the control group was observed. Similarly, after 1 year, LDL cholesterol had decreased statistically significantly more in both intervention groups compared to the control group (mean difference (MD) of -0.27 mmol/L (-0.49, -0.05) for intervention group 1 and -0.37 mmol/L (-0.59, -0.15) for intervention group 2, compared to the control group).

Risk of bias

In the RCT by Jenkins et al., the risk of attrition bias (due to a high drop-out rate of approximately 60%) was scored as high. Whether allocation was concealed and outcome assessors were blinded is unclear. The quality of the RCT by Karlström et al. was scored as high (based on GRADE). In the RCT by Kondo et al., the overall risk of bias was scored as low. In the RCT by Li et al., risk of selective reporting was scored as high but the authors did not motivate their judgment. Whether sequence generation was random, allocation was concealed and participants were blinded is unclear.

Funding

The foods used in the studies by Jenkins et al. and by Karlström et al. were donated by food companies (**Annex C**). Whether or not the funders were involved in the study was not reported and, therefore, the impact on the study findings remains unclear. For the other studies, no notable funding sources or conflicts of interests were reported.

Compliance

Compliance was good in the RCTs by Jenkins et al. and Kondo et al. Compliance was not reported in the RCTs by Karlström et al. and Li et al.

Summary

The Committee included four RCTs in the evaluation of the short-term effect of increased intake of fibre from whole grain foods on LDL cholesterol in people with type 2 diabetes. Two RCTs showed a statistically significant beneficial (reducing) effect of higher fibre intake on LDL cholesterol after 3 weeks to 30 days of follow-up. The two other RCTs (with a duration of 8 and 12 weeks) showed no statistically significant effect; one of those pointed in the direction of an unfavourable effect on LDL cholesterol, which may be a result of the high drop-out rate. Compliance with the intervention was generally good where reported. The single RCT included in the long-term evaluation showed a statistically significant beneficial (reducing) effect of increased fibre intake on LDL cholesterol after 1 year. The Committee noted differences in the effect size between studies, that cannot be directly explained by the study duration, sample size or fibre dose, but may have to do with the differences in intervention type between studies.

3.1.5 Systolic blood pressure

The scientific evidence for effects of increased intake of fibre from whole grain foods on systolic blood pressure in people with type 2 diabetes is described in Table 7.

Table 7 Summary of the effects of increased intake of fibre from whole grain foods on systolic blood pressure in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Jenkins et al., 2002[15]; 12 weeks	Kondo et al., 2017[17]; 8 weeks
Total number of participants (i/c)	23 (completers)	28 (14/14)
Study design	Cross-over, wash-out period of 2 months	Parallel
Fibre dose[a]; diet of intervention (i) and control (c) group	15 g prescribed, 16 g achieved; i: wheat bran added to bread and breakfast cereals, c: white bread and low-fibre breakfast cereals Isocaloric	4 g/d (achieved); i: brown rice, c: white rice Isocaloric
Result	Relative MD in post-intervention values: -1.5%, P=0.388	Mean change (95%CI): i: -2.9 mmHg (-9.7, 3.8) c: -4.8 mmHg (-12.2, 2.6) P=0.687
Study population	Adults with type 2 diabetes without insulin therapy; BMI[b]: 27 ± 1 kg/m^2; diabetes duration: 1-3 y (n=7), ≥3 y (n=16); diabetes medications: diet alone (n=4), diet and hypoglycaemic agents (n=19); men and (postmenopausal) women; Canada	Adults with type 2 diabetes without insulin therapy and with baseline HbA1c <8.4%; BMI[b]: 24 ± 4 kg/m^2 (i), 25 ± 4 kg/m^2 (c); diabetes duration[b]: 16 ± 10 y (i), 14 ± 7 y (c); diabetes medications: glucose-lowering agents (79% (i), 100% (c)); men and women; Japan

BMI: body mass index; c: control group; CI: confidence interval; d: days; i: intervention group; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; SEM: standard error of the mean; y: years.

[a] Fibre dose represents the difference in fibre intake between the intervention group and control group.

[b] Mean ± standard deviation.

The Committee concluded the following:

There is too little research to draw conclusions regarding the short-term effect of increased intake of fibre from whole grain foods on systolic blood pressure 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:

There are two RCTs, with far fewer than 90 participants (n=51), included in the evaluation. The number of studies and number of participants are too small to draw any conclusions.

Explanation:

The Committee included two RCTs, by Jenkins et al.[15] and Kondo et al.[17], in the evaluation of the effect of increased intake of fibre from whole grain foods on systolic blood pressure in people with type 2 diabetes. The RCTs have been described in more detail in section 3.1.1. Neither RCT showed a statistically significant effect of higher fibre intake, under isocaloric circumstances, on systolic blood pressure after eight to 12 weeks. The very small sample size may be an explanation.

3.2 Evidence from prospective cohort studies

The scientific evidence for associations of higher intake of fibre from whole grain foods with long-term health outcomes in people with type 2 diabetes is described in Table 8.

Table 8 Summary of the associations of intake of fibre from whole grain foods with long-term health outcomes in people with type 2 diabetes: prospective cohort studies.

Study; **study duration**	**He et al., 2010[31];** **26 years**
Study design	Individual cohort study
Cohort name	Nurses' Health Study (NHS)
Exposure(s)	Cereal fibre intake, bran intake, germ intake
Dietary assessment method	Semi-quantitative food frequency questionnaires administered at baseline and at 6 follow-up rounds (with intervals of 4 years); cumulative average was used
Number of participants; number of cases	7822 participants; All-cause mortality: 852 CVD mortality: 295
Strength of the association: RR (95%CI)	ALL-CAUSE MORTALITY: Q5 versus Q1 of cereal fibre intake: 0.86 (0.66-1.12)[a], P-trend: 0.10 Q5 versus Q1 of bran intake: 0.72 (0.56-0.92)[a], P-trend: 0.01 Q5 versus Q1 of germ intake: 0.99 (0.78-1.26)[a], P-trend: 0.69 CVD MORTALITY: Q5 versus Q1 of cereal fibre intake: 0.89 (0.57-1.41)[a], P-trend: 0.41 Q5 versus Q1 of bran intake: 0.65 (0.43-0.99)[a], P-trend: 0.04 Q5 versus Q1 of germ intake: 0.85 (0.58-1.25)[a], P-trend: 0.37
Study population	Participants with type 2 diabetes (diagnosed after age of 30 years); BMI (mean): 30 kg/m^2; diabetes duration: NR; diabetes medication; NR; women; USA

BMI: body mass index; CI: confidence interval; CVD: cardiovascular disease; NR: not reported; Q: quartile; RR: relative risk; USA: United States of America.

[a] Associations were adjusted for age, smoking status, BMI, alcohol intake, physical activity, parental history of MI, menopausal status and use of hormone therapy, duration of diabetes, energy intake, and intakes of polyunsaturated fat, saturated fat, *trans* fat, magnesium and folate.

The Committee concluded the following:

There is too little research to draw conclusions regarding the association of fibre intake from whole grain foods with the risk of all-cause 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:

There are no MAs of prospective cohort studies that address associations of fibre intake with risks of long-term health outcomes. There is only one individual prospective cohort study that addresses the association with all-cause mortality. That is too little evidence to base conclusions on.

There is too little research to draw conclusions regarding the association of fibre intake from whole grain foods with the risk of mortality due to CVD 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:

There are no MAs of prospective cohort studies that address associations of fibre intake with risks of long-term health outcomes. There is only one individual prospective cohort study that addresses the association with CVD mortality. That is too little evidence to base conclusions on.

Explanation:

The Committee included one prospective cohort study, by He et al.[31], in the evaluation of intake of fibre from whole grain foods with risks of all-cause mortality and CVD mortality in people with type 2 diabetes. The study, including 7800 participants and reporting 852 cases of all-cause mortality and nearly 300 cases of cardiovascular mortality, showed that higher bran intake was statistically significantly associated with a lower risk of all-cause mortality and CVD mortality. Cereal fibre intake and germ intake were not statistically significantly associated with all-cause mortality or CVD mortality. The authors reported that the non-significant associations may be due to the limited statistical power of the study.

Funding or author’s conflicts of interest did likely not affect the study findings of the study included in this evaluation (**Annex C**).

04
effects and associations of total fibre

4.1 Evidence from randomised controlled trials

4.1.1 HbA1c

The scientific evidence for effects of increased intake of total fibre on HbA1c in people with type 2 diabetes is described in Table 9.

Table 9 Summary of the effects of increased intake of total fibre on HbA1c in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Chandalia et al., 2000[20]; 6 weeks	Hollenbeck et al., 1986[21]; 4 weeks
Total number of participants	13	6
Study design	Cross-over, wash-out period of 7 days	Cross-over, no wash-out period
Fibre dose[a]; diet of intervention (i) and control (c) group	26 g/d (prescribed); i: diet according to the ADA guidelines with extra fibre (50 g; through adding or replacing various food sources including fruits, vegetables, legumes and grains), c: diet according to the ADA guidelines including 24 g of fibre Isocaloric	16 g/1000 kcal; i: high-fibre diet (27 g of fibre; through adding or replacing various food sources including grains, fruits and peanuts), c: low-fibre diet (11 g of fibre) Isocaloric
Result	Absolute MD in post-intervention values (95%CI)[b]: -0.3% (-0.6, 0.1) P=0.09	Absolute MD in post-intervention values[b]: NS (details not reported)
Study population	Adults with type 2 diabetes; BMI[c]: 32 ± 4 kg/m^2; diabetes duration: NR; diabetes medications: diet alone (n=3), diet and glucose-lowering agents (glyburide; n=10); men (n=12) and women (n=1); USA	Adults with non-insulin-dependent diabetes; BMI[c]: 26 ± 1 kg/m^2; diabetes duration: NR; diabetes medications: diet alone (n=2), glucose-lowering agents (n=4); sex: NR; USA

ADA: American Diabetes Association; BMI: body mass index; c: control group; CI: confidence interval; i: intervention group; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; USA: United States of America.

[a] Fibre dose represents the difference in fibre intake between the intervention group and control group.

[b] HbA1c usually is expressed in %. This change refers to the absolute change in HbA1c level, i.e. the difference between the post- and pre-intervention HbA1c level and not the relative change in HbA1c.

[c] Mean ± standard deviation.

The Committee concluded the following:

There is too little research to draw conclusions regarding the short-term effect of increased total fibre intake on HbA1c 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:

There are two RCTs, with far fewer than 90 participants (n=19), included in the evaluation. The number of studies and number of participants are too small to draw any conclusions.

Explanation:

Study characteristics and main effects

Chandalia et al.[20] examined the effect of a high-fibre diet on glycaemic control in people with type 2 diabetes. The RCT had a cross-over design with a wash-out period of 7 days. During the control phase, participants (n=13) followed a diet that met the dietary guidelines for diabetes patients as set by the American Diabetes Association (ADA). The diet is comprised of 55 E% of carbohydrate, 15 E% of protein, 30 E% of fat and included 24 g/d of fibre. During the intervention phase, participants received a similar diet (i.e. isocaloric and similar macronutrient distribution) but with a fibre content of 50 g/d. The higher fibre content in the diet was achieved through (adding or replacing) various food sources including fruits, vegetables, legumes and grains. All meals were provided by the research team.

The absolute difference in post-intervention data of HbA1c between intervention and control was used to examine the effect of increased fibre intake. Post-intervention HbA1c levels were on average 0.3% (95%CI: -0.1, 0.6) lower after the intervention phase compared to the control phase. This effect was borderline statistically significant (P=0.09). The intervention duration was 6 weeks per phase, which might have been too short to demonstrate a statistically significant effect on HbA1c as HbA1c reflects blood glucose levels over a period of 2 to 3 months.

Hollenbeck et al.[21] examined the effect of increased fibre intake, whilst the amount and source of carbohydrate as well as the source of dietary fibre were held constant, on parameters of glucose and lipid metabolism in people with non-insulin-dependent diabetes. The RCT had a cross-over design, presumably without a wash-out period. Participants (n=6) were admitted to the research centre for the entire study period and foods were provided by the research centre. During the control phase, participants received a low-fibre diet including 11 g of fibre per 1000 kcal and during the intervention phase, participants received a high-fibre diet including 27 g of fibre per 1000 kcal. Dietary fibre was increased in the high-fibre diet by replacing refined grain foods with whole gains foods, fruit juice with

whole fruits and by adding peanuts. Diets were isocaloric and similar in proportion of carbohydrate (60 E%), fat (25 E%) and protein (15 E%).

Post-intervention data on HbA1c were not reported but only shown graphically (from visual inspection, estimated to be around 6.8% after the intervention phase and around 7.0% after the control phase). The authors reported that post-intervention HbA1c levels were not statistically significantly different from baseline after either the intervention phase or the control phase. In addition, they reported that HbA1c values were remarkably similar for both phases. These findings suggest that there was no statistically significant effect of the high-fibre diet compared to the low-fibre diet on HbA1c. The short study duration may be a potential explanation. The Committee furthermore noted that participants in the RCT by Chandalia et al. had on average a higher BMI compared to the participants in the RCT by Hollenbeck et al., which may have contributed to the different results observed. Also, the type of intervention differed between the studies.

Risk of bias

Risk of bias in the RCT by Chandalia et al. and Hollenbeck et al. were judged in the MA by Post et al.[37] The study quality was scored as high for the RCT by Chandalia et al. and as moderate for the RCT by Hollenbeck et al. The authors did not motivate their judgment. The Committee noted that Hollenbeck et al. poorly reported the results of their study.

Funding

The funding sources of the evaluated studies and conflicts of interests of the authors are presented in **Annex C**. No notable funding sources or conflicts of interests were reported.

Compliance

In the RCT by Chandalia et al., dietitians monitored the compliance with the intervention through interviewing participants and calculating the energy content of unconsumed foods (returned by the participant). Compliance was reported to be very good. Information on compliance was not available in the RCT by Hollenbeck et al. It is, however, expected that compliance was overall good as the participants resided in the study centre during the entire duration of the trial, daily menus were provided by the research team and diets consisted of conventional foods.

Summary

The Committee included two RCTs in the evaluation of the effect of increased total fibre intake on HbA1c in people with type 2 diabetes. No statistically significant effect of higher fibre intake on HbA1c was observed in either study, although one RCT showed a tendency towards a greater reduction in HbA1c when consuming a high-fibre diet compared to a low-fibre diet for 6 weeks. In both studies, the study duration was relatively short (4-6 weeks) and study samples were small (n=6-13), which may have hindered the observation of a statistically significant effect.

Participants in the study tending to show a beneficial effect had, on average, a higher BMI compared to the participants in the other study, which may contribute to the discrepancy in results observed. Also the intervention type differed between those studies. Where reported, the compliance was generally good and risk of bias was moderate to low, which likely did not affect the results.

4.1.2 Fasting blood glucose

The scientific evidence for effects of increased intake of total fibre on fasting blood glucose in people with type 2 diabetes is described in Table 10.

The Committee concluded the following:

There is too little research to draw conclusions regarding the short-term effect of increased total fibre intake on fasting blood glucose 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:

There is only one RCT, with far fewer than 90 participants (n=6), included in the evaluation. The number of studies and number of participants are too small to draw any conclusions.

Explanation:

The Committee included one RCT, by Hollenbeck et al.[21], in the evaluation of the effect of increased total fibre intake on fasting blood glucose in people with type 2 diabetes (described in more detail in section 4.1.1). This RCT (n=6) showed no statistically significant effect of increased fibre intake on fasting blood glucose within 4 weeks.

Table 10 Summary of the effects of increased total fibre intake on fasting blood glucose in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Hollenbeck et al., 1986[21]; 4 weeks
Total number of participants	6
Study design	Cross-over, no wash-out period
Fibre dose[a]; diet of intervention (i) and control (c) group	16 g/1000 kcal; i: high-fibre diet (27 g of fibre; through adding or replacing various food sources including grains, fruits and peanuts), c: low-fibre diet (11 g of fibre) Isocaloric
Result	Mean (± SEM) post-intervention values: i: 194 ± 17 mg/dL c: 177 ± 19 mg/dL NS
Study population	Adults with non-insulin-dependent diabetes mellitus; BMI[b]: 26 ± 1 kg/m^2; diabetes duration: NR; diabetes medications: diet alone (n=2), glucose-lowering agents (n=4); sex: NR; USA

BMI: body mass index; c: control group; CI: confidence interval; i: intervention group; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; USA: United States of America.

[a] Fibre dose represents the difference in fibre intake between the intervention group and control group.

[b] Mean ± standard deviation.

4.1.3 Body weight

The scientific evidence for effects of increased intake of total fibre on body weight in people with type 2 diabetes is described in Table 11.

Table 11 Summary of the effects of increased total fibre intake on body weight in people with type 2 diabetes: individual randomised controlled trials.

Study; **study duration**	**Chandalia et al., 2000[20];** **6 weeks**
Total number of participants	13
Study design	Cross-over, wash-out period of 7 days
Fibre dose[a]; diet of intervention (i) and control (c) group	26 g/d (prescribed); i: diet according to the ADA guidelines with extra fibre (50 g; through adding or replacing various food sources including fruits, vegetables, legumes and grains), c: diet according to the ADA guidelines including 24 g of fibre Isocaloric
Result	MD in post-intervention values (95%CI): -0.2 kg (-1.1, 0.6), P=0.60
Study population	Adults with type 2 diabetes; BMI[b]: 32 ± 4 kg/m^2; diabetes duration: NR; diabetes medications: diet alone (n=3), diet and glucose-lowering agents (glyburide; n=10); men (n=12) and women (n=1); USA

ADA: American Diabetes Association; BMI: body mass index c: control group; CI: confidence interval; d: days; i: intervention group; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; USA: United States of America.

[a] Fibre dose represents the difference in fibre intake between the intervention group and control group.

[b] Mean ± standard deviation.

The Committee concluded the following:

There is too little research to draw conclusions regarding the short-term effect of increased total fibre intake on body weight 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:

There is only one RCT, with far fewer than 90 participants (n=13), included in the evaluation. The number of studies and number of participants are too small to draw any conclusions.

Explanation:

The Committee included one RCT, by Chandalia et al.[20], in the evaluation of the effect of increased total fibre intake on body weight in people with type 2 diabetes (described in more detail in section 4.1.1). No statistically significant effect was observed of a high-fibre diet, achieved through multiple food sources, compared to an isocaloric low-fibre diet with similar macronutrient distribution, on body weight within 6 weeks.

4.1.4 LDL cholesterol

The scientific evidence for effects of increased intake of total fibre on LDL cholesterol in people with type 2 diabetes is described in Table 12.

Table 12 Summary of the effects of increased total fibre intake on LDL cholesterol in people with type 2 diabetes: individual randomised controlled trials.

Study; study duration	Chandalia et al., 2000[20]; 6 weeks	Hollenbeck et al., 1986[21]; 4 weeks
Total number of participants	13	6
Study design	Cross-over, wash-out period of 7 days	Cross-over, no wash-out period
Fibre dose[a]; diet of intervention (i) and control (c) group	26 g/d (prescribed); i: diet according to the ADA guidelines with extra fibre (50 g; through adding or replacing various food sources including fruits, vegetables, legumes and grains), c: diet according to the ADA guidelines including 24 g of fibre Isocaloric	16 g/1000 kcal; i: high-fibre diet (27 g of fibre; through adding or replacing various food sources including grains, fruits and peanuts), c: low-fibre diet (11 g of fibre) Isocaloric
Result	MD in post-intervention values (95%CI): -0.23 mmol/L (-0.57, 0.08)[b], P=0.11	Mean (± SEM) post-intervention values: i: 3.07 mmol/L ± 0.29[b] c: 2.78 mmol/L ± 0.21[b] NS
Study population	Adults with type 2 diabetes; BMI[c]: 32 ± 4 kg/m^2; diabetes duration: NR; diabetes medications: diet alone (n=3), diet and glucose-lowering agents (glyburide; n=10); men (n=12) and women (n=1); USA	Adults with non-insulin-dependent diabetes mellitus; BMI[c]: 26 ± 1 kg/m^2; diabetes duration: NR; diabetes medications: diet alone (n=2), glucose-lowering agents (n=4); sex: NR; USA

BMI: body mass index; c: control group; CI: confidence interval; d: days; i: intervention group; MD: mean difference; NR: not reported; NS: not statistically significant; RCT: randomised controlled trial; USA: United States of America.

[a] Fibre dose represents the difference in fibre intake between the intervention group and control group.
[b] Values converted to mmol/L by multiplying the values in mg/dL by 0.026.
[c] Mean ± standard deviation.

The Committee concluded the following:

There is too little research to draw conclusions regarding the short-term effect of increased total fibre intake on LDL cholesterol 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:
There are two RCTs, with far fewer than 90 participants (n=19), included in the evaluation. The number of studies and number of participants are too small to draw any conclusions.

Explanation:

Two RCTs, by Chandalia et al.[20] and by Hollenbeck et al.[21], examined the effect of a high-fibre diet on LDL cholesterol in people with type 2 diabetes, which were described in more detail in section 4.1.1. Neither RCT showed a statistically significant effect on LDL cholesterol within 4 or 6 weeks.

4.2 Evidence from prospective cohort studies

The scientific evidence for associations of higher intake of total fibre with long-term health outcomes in people with type 2 diabetes is described in Table 13.

Table 13 Summary of the associations of increased total fibre intake with long-term health outcomes in people with type 2 diabetes: prospective cohort studies.

Study; study duration	Burger et al., 2012[30]; 9.2 years	Tanaka et al., 2013[32]; 8 years
Study design	Pooled analysis of 15 cohorts	Individual cohort study
Cohort name	EPIC	Japan Diabetes Complications Study
Exposure	Total fibre intake	Total fibre intake
Dietary assessment method	Self-administered, validated, country-specific dietary questionnaire at baseline, either quantitative dietary questionnaires with individual portion sizes or semi-quantitative food frequency questionnaires, or both	Validated food frequency questionnaire on food groups at baseline
Number of participants; number of cases	6192 participants; All-cause mortality: 791 CVD mortality: 306	1414 participants; (Non-)fatal stroke: 68 (Non-)fatal CHD: 96
Strength of the association: HR (95%CI)	Per 6.4 g/d higher intake of total fibre: ALL-CAUSE MORTALITY: 0.83 (0.75-0.91)[a] CVD MORTALITY: 0.76 (0.64-0.89)[a]	Per 1 g/d higher intake of total fibre: (NON-)FATAL CHD: 0.98 (0.90-1.06)[b], P=0.57 (NON-)FATAL STROKE: 0.82 (0.73-0.93)[b], P<0.01
Study population	Participants with self-reported diabetes (type 1 or 2); BMI[c]: 29 ± 5 kg/m^2; diabetes duration: 4.4 y (median); diabetes medication: glucose-lowering drugs (82%), insulin therapy (22%); men and women; Europe	Participants diagnosed with type 2 diabetes; BMI[c]: 23 ± 3 kg/m^2; diabetes duration[c]: 11 ± 7 y; diabetes medication: oral antihypertensive agents without insulin (65%), insulin (21%); men and women; Japan

BMI: body mass index; CI: confidence interval; CHD: coronary heart disease; CVD: cardiovascular disease; d; days; EPIC: European Prospective Investigation into Cancer and Nutrition; HR: hazard ratio; Q: quartile; y: years.

[a] Associations were stratified by sex and country, and adjusted for smoking, smoking duration, education, BMI, waist-to-hip ratio, physical activity, menopausal state, hormone replacement therapy use, alcohol intake, diabetes duration, insulin use, HbA1c, total energy intake and intakes of vitamin C, saturated fat, monounsaturated fat and polyunsaturated fat, and energy-adjusted carbohydrate intake.

[b] Associations were adjusted for age, sex, BMI, HbA1c, diabetes duration, diabetic retinopathy, treatment by insulin, treatment by oral hypoglycaemic agents, systolic blood pressure, LDL cholesterol, HDL cholesterol, triglycerides, current smoker, physical activity, alcohol intake and proportions of total fat, saturated fatty acids, n-6 fatty acids, n-3 fatty acids, dietary cholesterol, sodium intake and energy intake.

[c] Mean ± standard deviation.

The Committee concluded the following:

Prospective cohort studies show that a higher total fibre intake is associated with a 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 total fibre intake with risk of all-cause mortality. There is one pooled analysis of 15 cohorts, with more than 500 cases of mortality (n=791), that addresses 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 pooled analysis shows an inverse (beneficial) association between total fibre intake and risk of all-cause mortality. All centres are from the same study group (EPIC) and thus any dependency between (EPIC-) study centres cannot be ruled out. Since there is no other study that supports the results of the pooled analysis, the Committee judged the evidence as limited.

Prospective cohort studies show that a higher total fibre intake is associated with a lower risk of morbidity or mortality due to CVD 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 total fibre intake with risk of morbidity or mortality due to CVD. There is one pooled analysis of 15 cohorts and one individual cohort study, with in total 470 cases of CVD, that addresses associations of total fibre intake with total or subtypes of CVD. 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. There is a beneficial association in the pooled analysis including 300 CVD cases. In the additional individual cohort study, with 68 stroke cases and 96 cases of CHD, a similar (beneficial) association was observed for stroke but no association was observed for CHD. Therefore, the evidence is judged as limited.

There is too little research to draw conclusions regarding the association of total fibre intake with risk of morbidity or mortality due to CHD 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:

There are no MAs of prospective cohort studies that address associations of total fibre intake with risk of morbidity or mortality due to CHD. There is only one individual prospective cohort study that addresses this association. That is too little evidence to base conclusions on.

There is too little research to draw conclusions regarding the association of total fibre intake with risk of morbidity or mortality due to stroke 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:

There are no MAs of prospective cohort studies that address associations of total fibre intake with risk of morbidity or mortality due to stroke. There is only one individual prospective cohort study that addresses this association. That is too little evidence to base conclusions on.

Explanation:
One pooled analysis of 15 cohorts and one individual cohort study were found that addressed the association of total fibre intake with risk of CVD morbidity and/or mortality in people with type 2 diabetes.

The study by **Burger et al.**[30] is a pooled analysis of 15 cohorts from the European Prospective Investigation into Cancer and Nutrition (EPIC) study, covering six European countries. The study included almost 6200 participants. After a mean of 9 years follow-up, nearly 800 cases of all-cause mortality were reported, of which more than 300 cases were due to CVD.

Mean (± SD) fibre intake at baseline was 23.5 ± 6.4 g/d. This pooled analysis showed that higher total fibre intake was statistically significantly associated with a lower risk of all-cause mortality (HR per 6.4 g/d higher fibre intake 0.83, 95%CI 0.75, 0.91) and CVD mortality (HR 0.76, 95%CI 0.64, 0.89). For the outcome of all-cause mortality, the authors reported that no significant heterogeneity was observed between country-specific effect estimates (I^2: 0.0%). Heterogeneity was not reported for CVD mortality. The authors furthermore attempted to exclude people with type 1 diabetes by restricting the analyses to participants with an age at diabetes diagnosis above 40 years or to participants without insulin therapy. Neither analysis affected the conclusions. Therefore, the Committee considered the study by Burger et al. relevant for this advisory report.

The study by **Tanaka et al.**[32] included 1400 participants with type 2 diabetes. During the 8-year follow-up, 68 cases of stroke and 96 cases of CHD (combined morbidity and mortality) were reported.

Mean (± SD) fibre intake at baseline ranged from 8.7 ± 1.6 to 21.8 ± 4.0 g/d in quartiles (Q) 1 and 4 of total fibre intake, respectively. In this study, higher total fibre intake was statistically significantly associated with a lower risk of (non-)fatal stroke (HR per 1 g/d higher fibre intake 0.82, 95%CI 0.73-0.93). A similar association was observed for Q2 (HR 0.44, 95%CI 0.20-0.95) and Q3 (HR 0.37, 95%CI 0.15-0.91) but not for Q4 (HR 0.39, 95%CI 0.12-1.29) compared to Q1 of total fibre intake. Total fibre intake was not associated with risk of (non-)fatal CHD (HR per 1 g/d higher fibre intake 0.98, 95%CI 0.90-1.06; NS for Q4, Q3 and Q2 versus Q1).

Funding or author's conflicts of interest likely did not affect the study findings of the studies included in this evaluation (**Annex C**).

05
summary of conclusions

The Committee's conclusions regarding the relationships of fibre intake with health outcomes in people with type 2 diabetes are summarized in Table 14.

Table 14 Overview of conclusions regarding the relationship of higher fibre intake with health outcomes in people with type 2 diabetes, based on randomised controlled trials and prospective cohort studies.

Dietary exposure	Type of studies	Health outcome[a]	Conclusion
Fibre from whole grain foods	RCT	HbA1c	Short- term: Too little research Long-term: Too little research
Fibre from whole grain foods	RCT	Fasting blood glucose	Short-term: Inconclusive evidence Long-term: Too little research
Fibre from whole grain foods	RCT	Body weight	Short-term: Too little research Long-term: Too little research
Fibre from whole grain foods	RCT	LDL cholesterol	Short-term: Too little research Long-term: Too little research
Fibre from whole grain foods	RCT	Systolic blood pressure	Short-term: Too little research
Fibre from whole grain foods	Prospective cohort studies	All-cause mortality	Too little research
Fibre from whole grain foods	Prospective cohort studies	Mortality due to CVD	Too little research
Total fibre	RCT	HbA1c	Short-term: Too little research
Total fibre	RCT	Fasting blood glucose	Short-term: Too little research
Total fibre	RCT	Body weight	Short-term: Too little research
Total fibre	RCT	LDL cholesterol	Short-term: Too little research
Total fibre	Prospective cohort studies	All-cause mortality	Limited evidence for an inverse association
Total fibre	Prospective cohort studies	Morbidity or mortality due to CVD	Limited evidence for an inverse association
Total fibre	Prospective cohort studies	Morbidity or mortality due to CHD	Too little research
Total fibre	Prospective cohort studies	Morbidity or mortality due to stroke	Too little research

CHD: coronary heart disease; CVD: cardiovascular disease; HbA1c: glycated haemoglobin; LDL: low-density lipoprotein; NA: not applicable; RCT: randomised controlled trial.

[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.

references

1 Health Council of the Netherlands. *Dutch dietary guidelines for people with type 2 diabetes.* The Hague: Health Council of the Netherlands, 2021; publication no. 2021/41e.

2 Gezondheidsraad. *Voedingsvezel - Achtergronddocument bij Richtlijnen goede voeding 2015*. Den Haag: Gezondheidsraad, 2015; publicatienr. A15/30.

3 Health Council of the Netherlands. *Dutch dietary guidelines 2015*. The Hague: Health Council of the Netherlands, 2015; publication no. 2015/26E.

4 Health Council of the Netherlands. *Guideline for dietary fibre intake*. The Hague: Health Council of the Netherlands, 2006; publication no. 2006/03E.

5 van Rossum CTM, Buurma-Rethans EJM, Dinnissen CS, Beukers MH, Brants HAM, Dekkers ALM, et al. *The diet of the Dutch. Results of the Dutch National Food Consumption Survey 2012-2016*. Bilthoven: National Institute for Public Health and the Environment (RIVM), 2020; report no. 2020-0083.

6 Health Council of the Netherlands. *Fruit and vegetables. Background document to Dutch dietary guidelines for people with type 2 diabetes.* The Hague: Health Council of the Netherlands, 2021; publication no. 2021/41Be.

7 Health Council of the Netherlands. *Whole grain foods. Background document to Dutch dietary guidelines for people with type 2 diabetes.* The Hague: Health Council of the Netherlands, 2021; publication no. 2021/41Ce.

8 Stephen AM, Champ MM, Cloran SJ, Fleith M, van Lieshout L, Mejborn H, et al. *Dietary fibre in Europe: current state of knowledge on definitions, sources, recommendations, intakes and relationships to health*. Nutr Res Rev 2017; 30(2): 149-190.

9 Patterson MA, Maiya M, Stewart ML. *Resistant Starch Content in Foods Commonly Consumed in the United States: A Narrative Review*. J Acad Nutr Diet 2020; 120(2): 230-244.

10 McRorie JW, Jr. *Evidence-Based Approach to Fiber Supplements and Clinically Meaningful Health Benefits, Part 1: What to Look for and How to Recommend an Effective Fiber Therapy*. Nutr Today 2015; 50(2): 82-89.

11 McRorie JW, Jr. *Evidence-Based Approach to Fiber Supplements and Clinically Meaningful Health Benefits, Part 2: What to Look for and How to Recommend an Effective Fiber Therapy*. Nutr Today 2015; 50(2): 90-97.

12 Canfora EE, Meex RCR, Venema K, Blaak EE. *Gut microbial metabolites in obesity, NAFLD and T2DM*. Nat Rev Endocrinol 2019; 15(5): 261-273.

13 Liu F, Li P, Chen M, Luo Y, Prabhakar M, Zheng H, et al. *Fructooligosaccharide (FOS) and Galactooligosaccharide (GOS) Increase Bifidobacterium but Reduce Butyrate Producing Bacteria with*

Adverse Glycemic Metabolism in healthy young population. Sci Rep 2017; 7(1): 11789.

14 Health Council of the Netherlands. *Methodology for the evaluation of evidence. Background document to Dutch dietary guidelines for people with type 2 diabetes.* The Hague: Health Council of the Netherlands, 2021; publication no. 2021/41Ae.

15 Jenkins DJ, Kendall CW, Augustin LS, Martini MC, Axelsen M, Faulkner D, et al. *Effect of wheat bran on glycemic control and risk factors for cardiovascular disease in type 2 diabetes*. Diabetes Care 2002; 25(9): 1522-1528.

16 Karlstrom B, Vessby B, Asp NG, Boberg M, Gustafsson IB, Lithell H, et al. *Effects of an increased content of cereal fibre in the diet of Type 2 (non-insulin-dependent) diabetic patients*. Diabetologia 1984; 26(4): 272-277.

17 Kondo K, Morino K, Nishio Y, Ishikado A, Arima H, Nakao K, et al. *Fiber-rich diet with brown rice improves endothelial function in type 2 diabetes mellitus: A randomized controlled trial*. PLoS One 2017; 12(6): e0179869.

18 Li X, Cai X, Ma X, Jing L, Gu J, Bao L, et al. *Short- and Long-Term Effects of Wholegrain Oat Intake on Weight Management and Glucolipid Metabolism in Overweight Type-2 Diabetics: A Randomized Control Trial*. Nutrients 2016; 8(9): 549.

19 Stevens J, Burgess MB, Kaiser DL, Sheppa CM. *Outpatient management of diabetes mellitus with patient education to increase dietary carbohydrate and fiber*. Diabetes Care 1985; 8(4): 359-366.

20 Chandalia M, Garg A, Lutjohann D, von Bergmann K, Grundy SM, Brinkley LJ. *Beneficial effects of high dietary fiber intake in patients with type 2 diabetes mellitus*. N Engl J Med 2000; 342(19): 1392-1398.

21 Hollenbeck CB, Coulston AM, Reaven GM. *To what extent does increased dietary fiber improve glucose and lipid metabolism in patients with noninsulin-dependent diabetes mellitus (NIDDM)?* Am J Clin Nutr 1986; 43(1): 16-24.

22 Nederlandse Diabetes Federatie. *NDF Voedingsrichtlijn Diabetes*. Amersfoort, November 2020.

23 Cosentino F, Grant PJ, Aboyans V, Bailey CJ, Ceriello A, Delgado V, et al. *2019 ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD*. Eur Heart J 2020; 41(2): 255-323.

24 Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, et al. *Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report*. Diabetes Care 2019; 42(5): 731-754.

25 Diabetes UK 2018 Nutrition Working Group. *Evidence-based nutrition guidelines for the prevention and management of diabetes*. United Kingdom, 2018.

[26] Diabetes Canada Clinical Practice Guidelines Expert Committee, Sievenpiper JL, Chan CB, Dworatzek PD, Freeze C, Williams SL. *Nutrition Therapy*. Can J Diabetes 2018; 42 Suppl 1: S64-S79.

[27] Swedish Council on Health Technology Assessment. *Summary and Conclusions of the SBU Report: Dietary Treatment of Diabetes. A Systematic Review.* Stockholm, 2010.

[28] Reynolds AN, Akerman AP, Mann J. *Dietary fibre and whole grains in diabetes management: Systematic review and meta-analyses*. PLoS Med 2020; 17(3): e1003053.

[29] Wheeler ML, Dunbar SA, Jaacks LM, Karmally W, Mayer-Davis EJ, Wylie-Rosett J, et al. *Macronutrients, food groups, and eating patterns in the management of diabetes: a systematic review of the literature, 2010*. Diabetes Care 2012; 35(2): 434-445.

[30] Burger KN, Beulens JW, van der Schouw YT, Sluijs I, Spijkerman AM, Sluik D, et al. *Dietary fiber, carbohydrate quality and quantity, and mortality risk of individuals with diabetes mellitus*. PLoS One 2012; 7(8): e43127.

[31] He M, van Dam RM, Rimm E, Hu FB, Qi L. *Whole-grain, cereal fiber, bran, and germ intake and the risks of all-cause and cardiovascular disease-specific mortality among women with type 2 diabetes mellitus*. Circulation 2010; 121(20): 2162-2168.

[32] Tanaka S, Yoshimura Y, Kamada C, Tanaka S, Horikawa C, Okumura R, et al. *Intakes of dietary fiber, vegetables, and fruits and incidence of cardiovascular disease in Japanese patients with type 2 diabetes*. Diabetes Care 2013; 36(12): 3916-3922.

[33] Higgins JP, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. *The Cochrane Collaboration's tool for assessing risk of bias in randomised trials*. BMJ 2011; 343: d5928.

[34] Silva FM, Kramer CK, de Almeida JC, Steemburgo T, Gross JL, Azevedo MJ. *Fiber intake and glycemic control in patients with type 2 diabetes mellitus: a systematic review with meta-analysis of randomized controlled trials*. Nutr Rev 2013; 71(12): 790-801.

[35] He LX, Zhao J, Huang YS, Li Y. *The difference between oats and beta-glucan extract intake in the management of HbA1c, fasting glucose and insulin sensitivity: a meta-analysis of randomized controlled trials*. Food Funct 2016; 7(3): 1413-1428.

[36] Schünemann HJ, Higgins JPT, Vist GE, Glasziou P, Akl EA, Skoetz N, et al. *Chapter 14: Completing 'Summary of findings' tables and grading the certainty of the evidence.* Editor: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. Cochrane Handbook for Systematic Reviews of Interventions: Cochrane: 2020. www.training.cochrane.org/handbook.

[37] Post RE, Mainous Iii AG, King DE, Simpson KN. *Dietary fiber for the treatment of type 2 diabetes mellitus: A meta-analysis*. Journal of the American Board of Family Medicine 2012; 25(1): 16-23.

[38] Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults. *Executive Summary of The Third Report of The*

National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). JAMA 2001; 285(19): 2486-2497.

[39] Franz MJ, Powers MA, Leontos C, Holzmeister LA, Kulkarni K, Monk A, et al. *The evidence for medical nutrition therapy for type 1 and type 2 diabetes in adults*. J Am Diet Assoc 2010; 110(12): 1852-1889.

[40] Jovanovski E, Khayyat R, Zurbau A, Komishon A, Mazhar N, Sievenpiper JL, et al. *Should viscous fiber supplements be considered in diabetes control? Results from a Systematic Review and Meta-analysis of Randomized Controlled Trials*. Diabetes Care 2019; 42(5): 755-766.

[41] Wolfram T, Ismail-Beigi F. *Efficacy of high-fiber diets in the management of type 2 diabetes mellitus*. Endocr Pract 2011; 17(1): 132-142.

[42] Jovanovski E, Mazhar N, Komishon A, Khayyat R, Li D, Blanco Mejia S, et al. *Can dietary viscous fiber affect body weight independently of an energy-restrictive diet? A systematic review and meta-analysis of randomized controlled trials*. Am J Clin Nutr 2020; 111(2): 471-485.

[43] Shen XL, Zhao T, Zhou Y, Shi X, Zou Y, Zhao G. *Effect of Oat beta-Glucan Intake on Glycaemic Control and Insulin Sensitivity of Diabetic Patients: A Meta-Analysis of Randomized Controlled Trials*. Nutrients 2016; 8(1): 39.

[44] Ma X, Gu J, Zhang Z, Jing L, Xu M, Dai X, et al. *Effects of Avena nuda L. on metabolic control and cardiovascular disease risk among Chinese patients with diabetes and meeting metabolic syndrome criteria: secondary analysis of a randomized clinical trial*. Eur J Clin Nutr 2013; 67(12): 1291-1297.

annexes

A search strategies, study selection and flow diagrams

Systematic reviews including meta-analyses

The Committee performed a literature search to identify relevant systematic reviews (SRs) including meta-analyses (MAs) on the relationship between carbohydrate-containing food sources and health outcomes in people with type 2 diabetes. Literature searches were performed in PubMed and Scopus on 20th and 29th July 2020, respectively, using the following search strategies:

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: from 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)))) OR ((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: from 2000 + English

In total, 2054 publications were found in PubMed and 3887 publications in Scopus. After removal of duplicates, 4527 publications remained and were screened for title and abstract. A total of 172 publications remained for full-text assessment, of which 19 were selected for the Committee’s evaluation of carbohydrate quality.

Of those 19 publications, 14 publications concerned dietary fibre. None of those SRs or MAs fulfilled the Committee’s criteria. For example, because interventions of different fibre types were combined in one MA including studies using fibre supplements, or because studies among non-diabetic and diabetes patients were combined and no subgroup analyses were performed.

Due to the lack of relevant MAs, the Committee decided to retrieve relevant individual studies from SRs: nine SRs[28,34,35,37,39-43] included a relevant individual RCT. This resulted in a total of 8 RCTs that were relevant for the Committee’s evaluation of dietary fibre. The RCTs by Ma et al. (2013)[44] and Li et al. (2016)[18] concerned the same study population. The study population in the RCT by Ma et al. was a subgroup (i.e. diabetes patients with metabolic syndrome) of the study population (i.e. diabetes patients with or without metabolic syndrome) in the RCT by Li et al. The Committee selected the RCT with the largest sample, i.e. Li et al., for inclusion. Five of the remaining 7 RCTs were relevant for the evaluation of fibre from whole grain foods and 2 RCTs were relevant for the evaluation of total fibre.

The Committee selected the following five RCTs for its evaluation of fibre from whole grain foods:

- Jenkins et al., 2002[15]
- Karlström et al., 1984[16]
- Kondo et al., 2017[17]
- Li et al., 2016[18]
- Stevens et al., 1985[19]

The Committee selected the following two RCTs for its evaluation of total fibre:

- Chandalia et al., 2000[20]
- Hollenbeck et al., 1986[21]

Recent individual randomised controlled trials

The Committee performed three literature searches to identify relevant individual randomised controlled trials (RCTs) on the effect of dietary fibre on health outcomes in people with type 2 diabetes that were published after the inclusion date of the most recent SR/MA. Only health outcomes that were already covered in the selected SR/MA were included in the search. Literature searches were performed in PubMed and Scopus on 21st and 24th August 2020, respectively, using the following search strategies:

Fibre and DM2 outcomes[a]

PubMed

(“diabetes mellitus, type 2”[MeSH] OR Diabet*[tiab] OR T2DM[tiab] OR NIDDM[tiab]) AND (“dietary fiber”[MeSH] OR ((fiber[tiab] OR fibre[tiab]) AND (“diet”[MeSH] OR diet[tiab] OR dietary[tiab]))) AND (“Blood Pressure”[Mesh] OR blood pressure[tiab] OR Diastolic Pressure[tiab] OR Systolic Pressure[tiab] OR pulse pressure[tiab] OR “Insulin Resistance”[Mesh] OR insulin[tiab] OR glucose[tiab] OR glycemic control[tiab] OR glycaemic control[tiab] OR glycemia[tiab] OR glycaemia[tiab] OR “Glycated Hemoglobin A”[Mesh] OR HbA1c[tiab] OR Glycated Hemoglobin[tiab] OR Glycosylated Hemoglobin[tiab] OR HOMA-IR[tiab] OR “Cholesterol”[Mesh] OR cholesterol[tiab] OR LDL[tiab] OR HDL[tiab] OR “Body Weight”[Mesh] OR “Body Mass Index”[Mesh] OR weight[tiab] OR overweight*[tiab] OR BMI[tiab] OR “fructosamine”[MeSH] OR fructosamine[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 randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled*[tiab] OR placebo[tiab] OR clinical trial[tiab] OR trial[tiab] OR intervention[tiab])

[a] DM2 outcomes include: HbA1c, fasting blood glucose, glycaemia, fasting insulin, HOMA-IR (Homeostatic Model Assessment for Insulin Resistance), body weight, body mass index, blood pressure, cholesterol and fructosamine.

Limit: from 2018 + English

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
((KEY (dietary AND fiber) OR TITLE-ABS (dietary AND fiber)) OR ((TITLE-ABS (fiber) OR TITLE-ABS (fibre)) AND (KEY (diet) OR TITLE-ABS (diet) OR TITLE-ABS (dietary)))) AND ((KEY (blood AND pressure) OR TITLE-ABS (blood AND pressure) OR TITLE-ABS (diastolic AND pressure) OR TITLE-ABS (systolic AND pressure) OR TITLE-ABS (pulse AND pressure)) OR (KEY (insulin AND resistance) OR TITLE-ABS (insulin) OR TITLE-ABS (glucose) OR TITLE-ABS (glycemic AND control) OR TITLE-ABS (glycaemic AND control) OR TITLE-ABS (glycemia) OR TITLE-ABS (glycaemia) OR KEY (glycated AND hemoglobin AND a) OR TITLE-ABS (glycated AND hemoglobin AND a) OR TITLE-ABS (hba1c) OR TITLE-ABS (glycated AND hemoglobin) OR TITLE-ABS (glycosylated AND hemoglobin)) OR (TITLE-ABS (homa-ir) OR KEY (cholesterol) OR TITLE-ABS (cholesterol) OR TITLE-ABS (ldl) OR TITLE-ABS (hdl) OR KEY (body AND weight) OR TITLE-ABS (body AND weight) OR KEY (body AND mass AND index) OR TITLE-ABS (body AND mass AND index) OR TITLE-ABS (weight) OR TITLE-ABS (overweight*) OR TITLE-ABS (bmi) OR KEY (fructosamine) OR TITLE-ABS (fructosamine))) AND ((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 (randomized) OR TITLE-ABS (randomised) 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: from 2018 + English

In total, 127 publications were found in PubMed and 186 publications in Scopus. After removal of duplicates, 220 publications remained and were screened for title and abstract. A total of 18 publications remained for full-text assessment. None of these fulfilled the Committee's criteria and therefore could not be selected for the evaluation of dietary fibre.

Fibre and CVD outcomes

PubMed
("diabetes mellitus, type 2"[MeSH] OR Diabet*[tiab] OR T2DM[tiab] OR NIDDM[tiab]) AND ("dietary fiber"[MeSH] OR ((fiber[tiab] OR fibre[tiab]) AND ("diet"[MeSH] OR diet[tiab] OR dietary[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]) 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 randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled*[tiab] OR placebo[tiab] OR clinical trial[tiab] OR trial[tiab] OR intervention[tiab])

Limit: from 2009 + English

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 ((KEY (dietary AND fiber) OR TITLE-ABS (dietary AND fiber)) OR ((TITLE-ABS (fiber) OR TITLE-ABS (fibre)) AND (KEY (diet) OR TITLE-ABS (diet) OR TITLE-ABS (dietary)))) AND (TITLE-ABS-KEY (cardiovascular AND diseases) OR TITLE-ABS-KEY (heart AND diseases) OR TITLE-ABS-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 (cerebrovascular 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)) AND ((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 (randomized) OR TITLE-ABS (randomised) 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: from 2009 + English

In total, 103 publications were found in PubMed and 265 publications in Scopus. After removal of duplicates, 298 publications remained and were screened for title and abstract. A total of 7 publications remained for full-text assessment. None of these fulfilled the Committee's criteria and therefore could not be selected for the evaluation of dietary fibre.

Beta-glucan and DM2 outcomes[a]

PubMed

("diabetes mellitus, type 2"[MeSH] OR Diabet*[tiab] OR T2DM[tiab] OR NIDDM[tiab]) AND ("beta-glucans"[MeSH] OR beta glucan*[tiab] OR

[a] DM2 outcomes include: HbA1c, fasting blood glucose, glycaemic control, fasting insulin, HOMA-IR (Homeostatic Model Assessment for Insulin Resistance), and cholesterol.

beta-glucan*[tiab]) AND (“Insulin Resistance”[Mesh] OR insulin[tiab] OR glucose[tiab] OR glycemic control[tiab] OR glycaemic control[tiab] OR glycemia[tiab] OR glycaemia[tiab] OR “Glycated Hemoglobin A”[Mesh] OR HbA1c[tiab] OR Glycated Hemoglobin[tiab] OR Glycosylated Hemoglobin[tiab] OR HOMA-IR[tiab] OR “Cholesterol”[Mesh] OR cholesterol[tiab] OR LDL[tiab] OR HDL[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 randomized[tiab] OR randomised[tiab] OR RCT[tiab] OR controlled*[tiab] OR placebo[tiab] OR clinical trial[tiab] OR trial[tiab] OR intervention[tiab])

Limit: from 2014 + English

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-KEY (beta-glucans) OR TITLE-ABS (beta AND glucan*) OR TITLE-ABS (beta-glucan*)) AND ((TITLE-ABS-KEY (insulin AND resistance) OR TITLE-ABS (insulin) OR TITLE-ABS (glucose) OR TITLE-ABS (glycemic AND control) OR TITLE-ABS (glycaemic AND control) OR TITLE-ABS (glycemia) OR TITLE-ABS (glycaemia) OR TITLE-ABS-KEY (glycated AND hemoglobin AND a) OR TITLE-ABS (hba1c) OR TITLE-ABS (glycated AND hemoglobin) OR TITLE-ABS (glycosylated AND hemoglobin) OR (TITLE-ABS (homa-ir) OR KEY (cholesterol) OR TITLE-ABS (cholesterol) OR TITLE-ABS (ldl) OR TITLE-ABS (hdl)) AND ((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 (randomized) OR TITLE-ABS (randomised) 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: from 2014 + English

In total, 23 publications were found in PubMed and 22 publications in Scopus. After removal of duplicates, 28 publications remained and were screened for title and abstract. A total of 3 publications remained for full-text assessment. None of these fulfilled the Committee’s criteria and therefore could not be selected for the evaluation of dietary fibre.

Prospective cohort studies

Since no SRs or MAs of (multiple) cohort studies were found, the Committee searched for individual prospective cohort studies on associations of fibre intake with health outcomes in the retrieved SRs and in external dietary guidelines for diabetes of the following organisations:

- Dutch Diabetes Federation (Nederlandse Diabetes Federatie (NDF)), 2020[22]
- European Association for the Study of Diabetes (EASD) & European Society of Cardiology (ESC), 2020[23]
- American Diabetes Association (ADA), 2019[24]
- Diabetes UK, 2018[25]
- Diabetes Canada, 2018[26]
- Swedish Council, 2010[27]

Two prospective cohort studies[30,31] were found via the SRs of Wheeler et al.[29] and Reynolds et al.[28] and were also included in the dietary guidelines for diabetes of the American Diabetes Association.[24] Subsequent screening of articles citing those cohort studies in PubMed yielded one additional relevant cohort study.[32] Further screening external dietary guidelines yielded no additional studies. One of those three cohort studies was relevant for the evaluation of fibre from whole grain foods, and two cohort studies were relevant for the evaluation of total fibre.

The Committee selected the following prospective cohort study for its evaluation of fibre from whole grain foods:

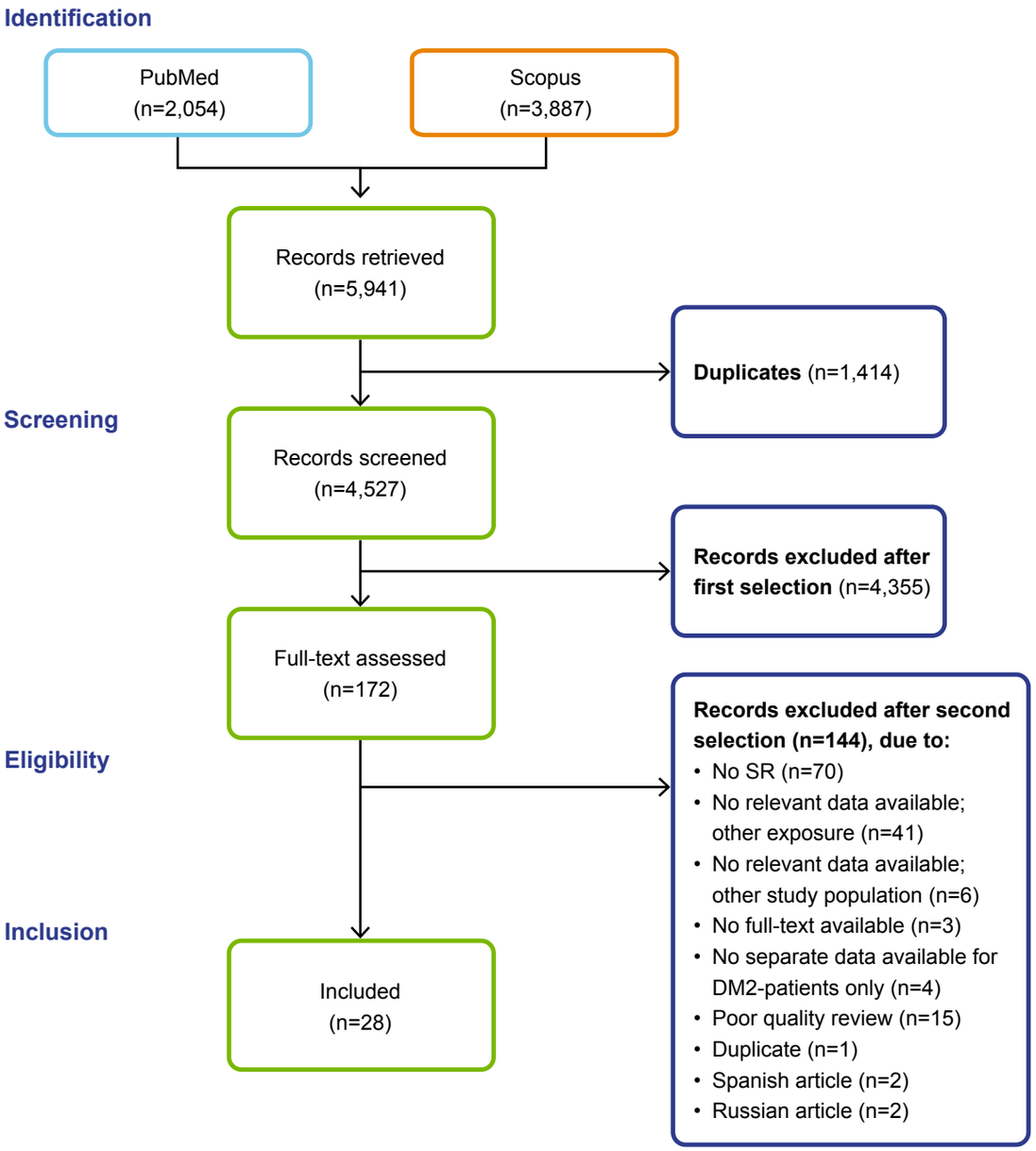
- He et al., 2010[31]

The Committee selected the following two prospective cohort studies for its evaluation of total fibre:

- Burger et al., 2012[30] (pooled analysis of prospective cohort studies)
- Tanaka et al., 2013[32]

Flow diagram for the selection of systematic reviews including meta-analyses

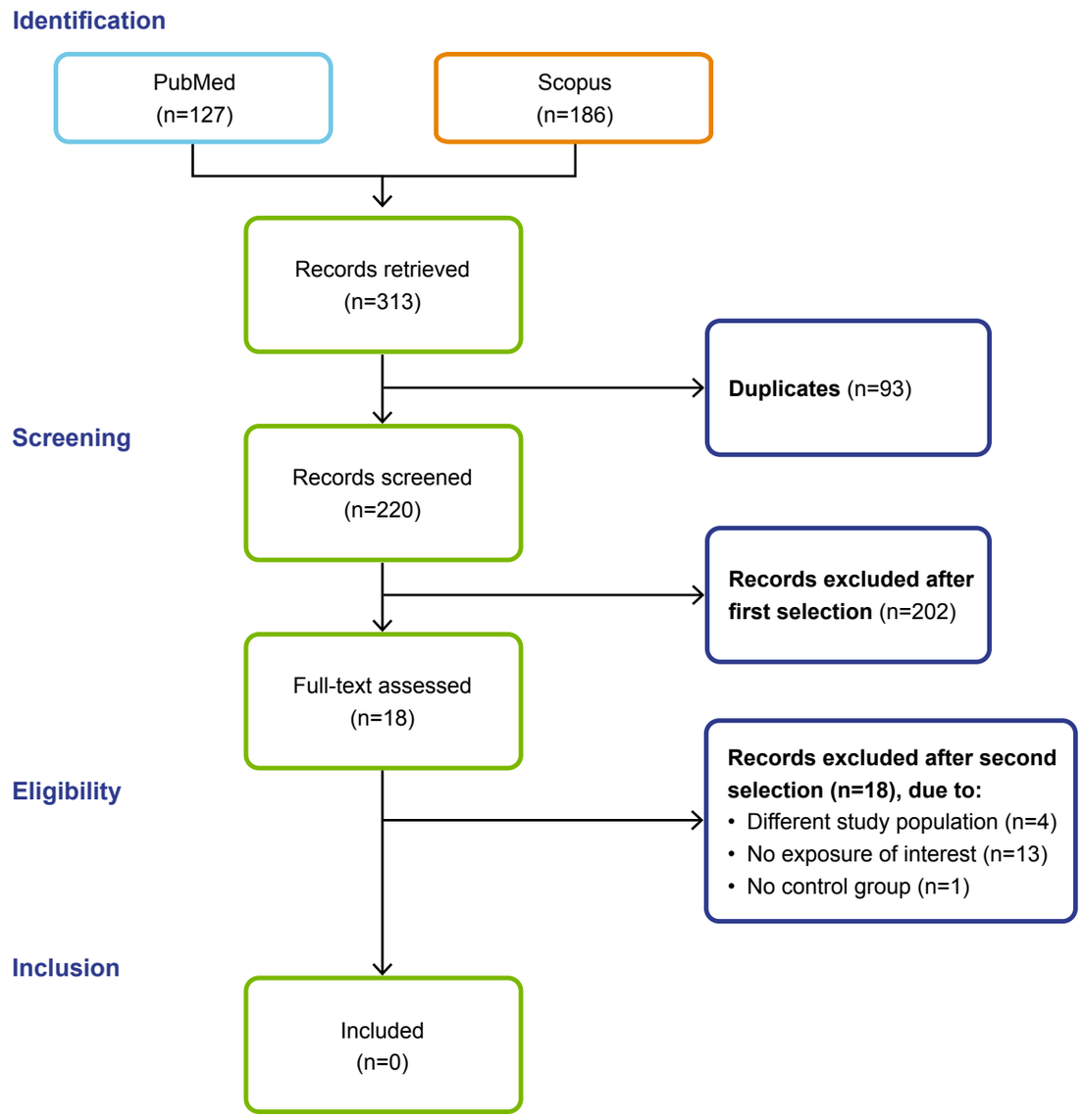
Carbohydrate containing foods and DM2



DM2: type 2 diabetes

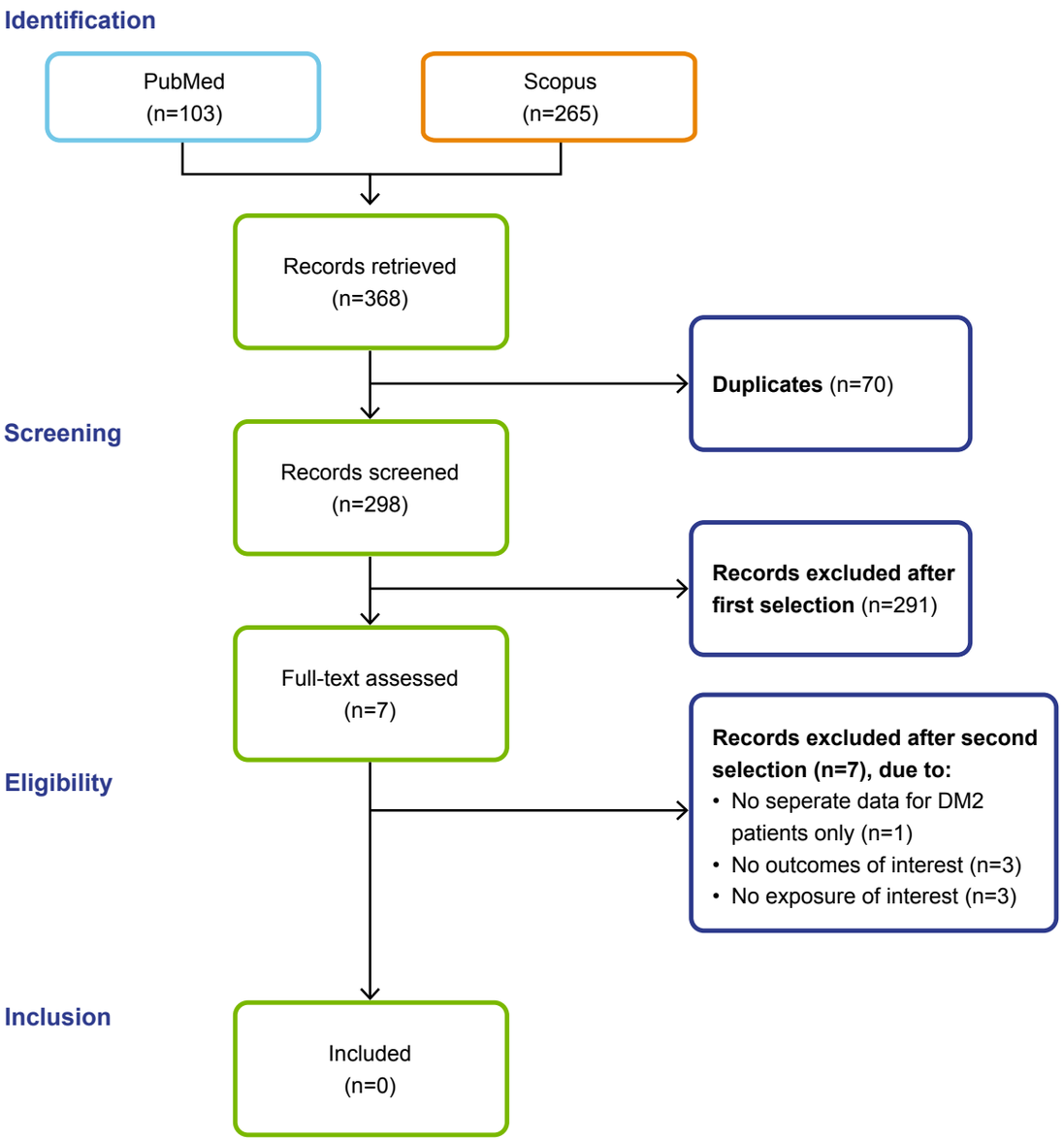
Flow diagrams for the selection of randomised controlled trials

Fibre and DM2 outcomes[a]



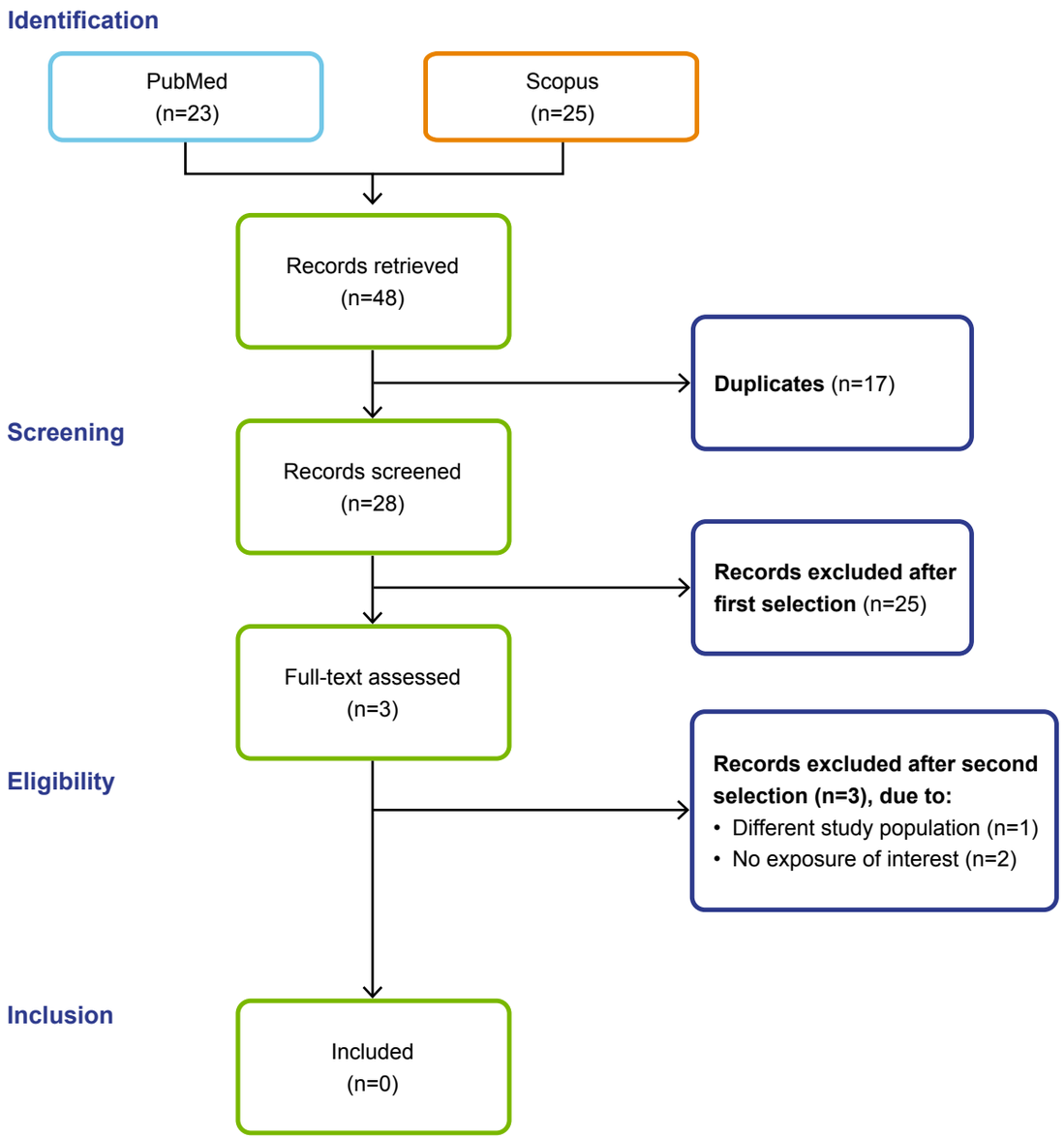
[a] DM2 (type 2 diabetes) outcomes include: HbA1c, fasting blood glucose, glycaemia, fasting insulin, HOMA-IR (Homeostatic Model Assessment for Insulin Resistance), body weight, body mass index, blood pressure, cholesterol and fructosamine.

Fibre and CVD outcomes



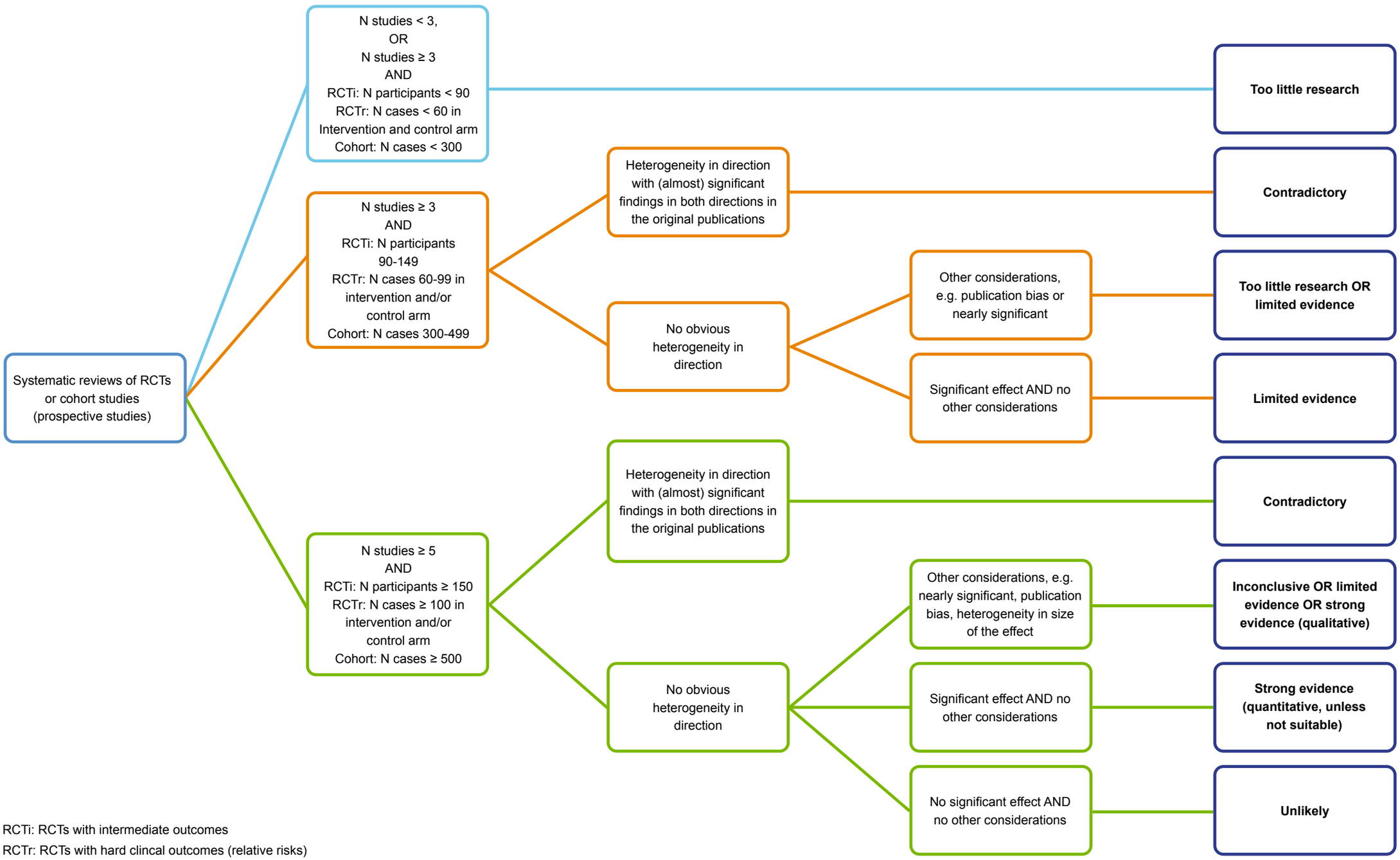
CVD: cardiovascular disease; DM2: type 2 diabetes

Beta-glucan and DM2 outcomes[a]



[a] DM2 (type 2 diabetes) outcomes include: HbA1c, fasting blood glucose, glycaemic control, fasting insulin, HOMA-IR (Homeostatic Model Assessment for Insulin Resistanc) and cholesterol.

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's first author, year	Funding of the work	Conflicts of interest of authors
Burger, 2012[30]	The study was supported by a European Foundation for the Study of Diabetes (EFSD)/ Sanofi-Aventis grant.	The authors declared to have no conflicts of interests.
Chandalia, 2000[20]	The study was supported by the National Institutes of Health, the Bundesministerium für Bildung, Forschung, Wissenschaft und Technologie (English: Federal Ministry for Education, Research, Science and Technology) and the Deutsche Forschungsgemeinschaft (English: German Research Foundation).	No information provided.
He, 2010[31]	The study was supported by the National Institutes of Health and the American Heart Association. The last author received a grant from the Boston Obesity Nutrition Research Center.	The authors declared to have no conflicts of interests.
Hollenbeck, 1986[21]	The study was supported by the Research Service of the Veterans Administration and National Institutes of Health.	No information provided.
Jenkins, 2002[15]	The study was funded by the Natural Sciences and Engineering Research Council of Canada. Study foods were supplied by several food companies (Loblaw Brands Limited, Kraft Canada and Parrheim Foods).	No information provided.
Karlström, 1984[16]	The study was supported by the Swedish Diabetic Association, the Swedish Medical Research Council and the Uppsala Hemsysterskola Foundation. Study foods were supplied by Wasa Bröd (food company).	No information provided.
Li, 2016[18]	The study was supported by the Inner Mongolia Sanzhuliang Natural Oats Industry Corporation (IMSNOIC).	The authors declared to have no conflicts of interests.
Stevens, 1985[19]	The study was supported by the University of Virginia Diabetes Research and Training Center and the University of Virginia School of Medicine Research and Development Committee.	No information provided.
Tanaka, 2013[32]	The study was financially supported by the Ministry of Health, Labour and Welfare of Japan.	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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