Intake of free sugars, chronic metabolic diseases and dental caries: inclusion/exclusion criteria

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SUB-QUESTIONS 5 AND 6 - METHODS

What is the relationship between the intake of free sugars from all dietary sources and chronic metabolic diseases (sub-Q5) / dental caries (sub-Q6) in the target population?

Systematic reviews

Dose-response meta-analyses, if possible

Human data only

SUB-QUESTIONS 5 AND 6 – ELIGIBILITY CRITERIA

❑ Publication type

	Intervention and observational studies
In	- Primary research studies (i.e. studies generating new data) reported in full-text articles - Primary research studies reported in letters to editors if the information provided is sufficient to allow a scientific evaluation - Systematic reviews and meta-analyses*
Out	- Narrative reviews, expert opinions, editorials and letters to editors not reporting on primary data - Meetings' abstracts and posters - Conference proceedings - PhD theses - Grey literature

** For the purpose of reviewing the reference list as source of primary data only*

SUB-QUESTIONS 5 AND 6 – ELIGIBILITY CRITERIA

- **Study design**

	Intervention studies	Observational studies
In	Randomised controlled trials Non-randomised comparative studies of interventions	Prospective, longitudinal, observational studies (prospective cohort and nested case-control)
Out	Single-arm, no control group	Retrospective case-control studies Cross-sectional studies Ecological studies Case studies/case series

- **Study location:** Any
- **Language:** Full-text in English
- **Publication year:** up to March 2018

SUB-QUESTIONS 5 AND 6– ELIGIBILITY CRITERIA

❑ Study population

	Intervention studies	Observational studies
In	- Adults and children from the general population, including overweight or obese - At risk of disease - With one or more features of the metabolic syndrome but not on pharmacological treatment	- Adults and children form the general population - At risk of disease - Studies in which prevalent cases of the disease endpoint of interest at baseline were excluded for data analysis
Out	- Studies targeting individuals with a disease (except for obesity), or individuals on a therapeutic diet, including weight-loss diets - Studies in individuals under physical training programs	- Studies targeting individuals with a disease (except for obesity) - Studies in which prevalent cases of the disease outcome of interest at baseline were not excluded for data analysis

SUB-QUESTIONS 5 AND 6– ELIGIBILITY CRITERIA

❑ Intervention (intervention studies)

IN:

- a quantitative change in the intake of free sugars, whether total or from one or more dietary sources
- a change in the intake of one or more dietary sources of free sugars which allows quantification of free sugars intake from those sources
- free sugars provided in addition to the usual diet or in replacement of other macronutrients; a restriction in the intake of free sugars (whether total or from one or more dietary sources)

OUT:

- studies not providing sufficient information to allow quantitative estimates of free sugars intake, whether total or from one or more dietary sources (e.g. studies reporting only on the frequency of consumption of one or more dietary sources of free sugars)
- changes in free sugars intake in the context of energy-restricted diets

SUB-QUESTIONS 5 AND 6– ELIGIBILITY CRITERIA

❑ Control (intervention studies)

IN:

- differs from the intervention on the amount of free sugars only - any effect can be attributed to the type/amount of free sugars consumed

OUT:

- differs from the intervention regarding characteristics other than the amount of free sugars which could affect the endpoints (e.g. dental hygiene and fluoridation for dental caries)

SUB-QUESTIONS 5 AND 6– ELIGIBILITY CRITERIA

❑ Exposure (observational studies)

IN:

- studies providing quantitative estimates of free sugars intake, whether total or from one or more dietary sources (in amount per day, in amount per kg/bw/day, or as % of total energy intake)
- studies providing sufficient information to allow quantitative estimates of free sugars intake, whether total or from one or more dietary sources

Eating conditions: *ad libitum*

OUT:

- studies not providing sufficient information to allow quantitative estimates of free sugars intake, whether total or from one or more dietary sources (e.g. studies reporting only on the frequency of consumption of one or more dietary sources of free sugars)

Eating conditions: *under dietary controlled conditions prior to the intake assessment*

SUB-QUESTIONS 5 AND 6– ELIGIBILITY CRITERIA

❑ Methods to assess the intake of free sugars

IN:

- Controlled feeding (food provided) – for interventions
- 24-h urinary excretion of fructose and sucrose
- Food records
- Diet recalls
- FFQs

OUT:

- Any other method

SUB-QUESTIONS 5 AND 6– ELIGIBILITY CRITERIA

❑ Study duration: based on expert knowledge

- Minimum study duration for the inclusion of **intervention studies (sub-Q5)**: selected by considering the **time generally required for the stabilisation of the surrogate endpoints** assessed following a nutritional intervention.

- Minimum study duration for the inclusion of **intervention studies** (**sub-Q 6**) and **observational studies** (**sub-Q 5 and 6**): based on the **minimum time estimated** to be needed **for the disease to develop** in individuals free of the disease at baseline.

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Study duration: chronic metabolic disease (and surrogate) endpoints**

	Intervention studies	Observational studies
In	Depending on the surrogate endpoints addressed, as follows: Adipose tissue ≥ 6 weeks Glucose homeostasis ≥ 1 week Cardiovascular system ≥ 4 weeks Liver function ≥ 2 week	≥ 1 year follow-up
Out	Studies of shorter duration	< 1 y follow-up

SUB-QUESTION 6 – ELIGIBILITY CRITERIA

❑ Study duration: dental caries

	Intervention and observational studies
In	Studies lasting at least one year for primary dentition and at least 18 months for permanent dentition
Out	Studies lasting < 1 year for primary dentition and < 18 months for permanent dentition

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **INTERVENTION studies** (IN/OUT)

Adipose tissue:

- Measured (self-reported) body weight, BMI, WC, sagittal diameter
- Body composition: body fat, lean body mass by NAA, imaging techniques (DXA, CT, MRI), hydrostatic weighing or ADP (measured by BIA or skinfold thickness).
- VAT assessed by imaging techniques (CT, MRI)
- Ectopic fat deposition in muscle assessed by muscle biopsies or MRS

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **INTERVENTION studies** (IN)

Glucose homeostasis:

- Dynamic indices of insulin sensitivity and/or beta-cell function calculated from measures of plasma glucose, serum insulin and C-peptide (when available) during clamp tests (hyperinsulinaemic-euglycaemic, hyperglycaemic), FSIGT, standard OGTT, the CIGMA, or insulin suppression tests

- Static indices of insulin sensitivity and/or beta-cell function calculated from fasting plasma glucose and fasting serum insulin (e.g. HOMA, QUICKI)

- Indices of blood glucose control (HbA1c, fructosamine)

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **INTERVENTION studies** (IN/OUT)

Cardiovascular system:

- SBP and DBP (point or 24-h BP)
- Blood lipids (total-c, LDL-c, HDL-c, VLDL-c, fasting TG, apoB100, apoA1, and ratios thereof)

Liver function:

- Liver fat accumulation measured by CT, MRI, MRS, or liver biopsies (ecography)
- NAFLD/NASH activity scores as defined by the authors

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **INTERVENTION studies**

OUT:

Studies not including at least one of the endpoints listed before

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **OBSERVATIONAL studies** (IN/OUT/observational studies only)

Adipose tissue:

- Measured (self-reported) body weight, BMI, WC, sagittal diameter
- Body composition: body fat, lean body mass by NAA, imaging techniques (DXA, CT, MRI), hydrostatic weighing, ADP, BIA or skinfold thickness.
- Incidence of overweight/obesity as defined by the authors

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **OBSERVATIONAL studies** (IN/observational studies only)

Glucose homeostasis:

- Static indices of insulin sensitivity and/or beta-cell function calculated from fasting plasma glucose and fasting serum insulin (e.g. HOMA, QUICKI)
- Indices of blood glucose control (HbA1c, fructosamine)
- Incidence of type 2 diabetes as defined by the authors
- Incidence of impaired glucose tolerance or impaired fasting glucose as defined by the authors

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**

  - **OBSERVATIONAL studies** (IN/observational studies only)

Cardiovascular system:

- SBP and DBP (point or 24-h BP)
- Incidence of hypertension as defined by the authors
- Blood lipid profile (as for interventions)
- Incidence of dyslipidaemia as defined by the authors
- Incidence of stroke [haemorrhagic (intracerebral, subarachnoid) and/or ischaemic; fatal and/or non-fatal]
- Incidence of CHD (fatal and/or non-fatal)
- Incidence of MI (fatal and/or non-fatal)
- Incidence of congestive heart failure
- Incidence of cardiac death
- Incidence of fatal and/or non-fatal CV events (composite outcome)
- Other endpoints of fatal and/or non-fatal CV events as defined by the authors

SUB-QUESTION 5 – ELIGIBILITY CRITERIA

- **Endpoints of interest: chronic metabolic diseases**
  - **OBSERVATIONAL studies** (IN/OUT/observational studies only)

Liver function:

- Liver fat accumulation measured by CT, MRI, MRS, or liver biopsies (ecography)
- NAFLD/NASH activity scores as defined by the authors
- Incidence of non-alcoholic liver fibrosis/cirrhosis/liver failure as defined by the authors

SUB-QUESTION 6 – ELIGIBILITY CRITERIA

- **Endpoints of interest: dental caries**
  - **INTERVENTION and OBSERVATIONAL studies**

IN:

- Indices of dental caries measured by a trained observer

OUT:

- Dental caries self-reported or reported by parents
- Surrogate endpoints (e.g. amount of dental plaque; plaque pH)

INCLUSIONS AND EXCLUSIONS CRITERIA