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Taxation of the fat content of foods for reducing their consumption and preventing obesity or other adverse health outcomes (Protocol)

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[Intervention Protocol]

Taxation of the fat content of foods for reducing their consumption and preventing obesity or other adverse health outcomes

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of taxation of fat content in food on consumption of total fat and saturated fat, energy intake, overweight, obesity, and other adverse health outcomes in the general population.

BACKGROUND

Description of the condition

Overweight and obesity, i.e. a body mass index (BMI) \geq 25 and a BMI \geq 30, respectively, are increasing worldwide and considered to be a major public health challenge of the 21st century (WHO 2014; NCD-RisC 2016). The Global Burden of Disease study estimated that the prevalence of obesity more than doubled between 1980 and 2013 (Ng 2014). In 2013, approximately 38%

of all adults had a BMI of more than 25; that is, about 2 billion people, of whom about a third were considered obese. Similarly, approximately 24% of all children worldwide were estimated to be overweight or obese. Although the increase of adult obesity has stabilised (albeit at very high levels) in some high-income countries (HICs), the prevalence of obesity in low- and middle-income countries (LMICs) and several HICs is continuing to rise (Ng 2014; Seidell 2015). The reasons for these trends are complex and influenced by a broad variety of social determinants of health, such as urbanisation, changes in types of employment, and alterations

to the food supply (Lang 2009). In LMICs the rise has been partly attributed to economic modernisation and lifestyle changes, i.e. a nutrition transition to a 'Western diet' that is broadly defined by high intake of refined carbohydrates, added sugars, fats, and animal-source foods (Goryakin 2015; Popkin 2012).

Obesity is a major risk factor for mortality and morbidity (Lhachimi 2013). In 2010, overweight and obesity were estimated to cause 3.4 million deaths, contributed 3.9% of years of life lost, and 3.8% to the global burden of disease (measured in disabilityadjusted life years) (Ng 2014). In particular non-communicable diseases (NCDs), such as type 2 diabetes, cardiovascular diseases (CVDs), certain cancers, and musculoskeletal disorders, are potential health consequences of a raised BMI (Guh 2009). This also makes obesity a significant factor for disability (Lhachimi 2016). NCDs are already the leading cause of death in HICs and are on the rise in LMICs (WHO 2014). Moreover, the increased prevalence of chronic diseases in regions where individuals have insufficient access to appropriate health care may exacerbate the harmful consequences of obesity on morbidity and mortality for those populations. For example, if an obese person with type 2 diabetes does not have regular access to insulin, this may result in particularly premature death, disability, or morbidity (Seidell 2015).

Overweight and obesity are often defined as the "abnormal or excessive body fat accumulation in adipose tissue" (WHO 2000; WHO 2011). At the individual level, overweight and obesity are mainly caused by an imbalance in energy intake and energy expenditure. The member states of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in their 2014 Declaration of Rome on Nutrition noted certain aspects of a diet that increase the susceptibly to both overweight and obesity, as well as comorbid NCDs; chief among them consumption of food that is high in fat (FAO/WHO 2015). Fats are energy dense (i.e. 37 kJ or 9 kcal per gram), a contributor to the palatability of food, and enable absorption of fat-soluble vitamins. Moreover, fats are crucial for development and survival during the early stages of life, i.e. embryonic development, early growth after birth, and childhood (Burlingame 2009). Excess fat intake, however, is associated with the rise in obesity. The consumption of particular types of fat has been linked to a range of diseases and adverse health outcomes, such as type 2 diabetes, coronary heart disease (CHD), stroke, and certain types of cancer (FAO 2010).

Dietary fats are conventionally grouped into three broad groups based on the number of double bonds the molecules exhibit, i.e. (i) saturated fatty acids, (ii) monounsaturated fatty acids, and (iii) polyunsaturated fatty acids. Saturated fats are acids with only single bonds between adjacent carbon atoms, i.e. every carbon atom carries its full quota of hydrogen atoms (Bender 2014). The most notable dietary sources of saturated fats are animal products such as meat, cow's milk, eggs, butter, and salmon. Plant products, such as palm oil, coconut, and chocolate/cocoa butter, are also substantial sources of dietary saturated fat intake (Souza 2015). Unsaturated fatty acids have one or more double bonds between carbon atoms:

monounsaturated fatty acids have only one of those double bonds whereas polyunsaturated fatty acids have two or more. Monounsaturated fatty acids can be found in animal and vegetable products such as red meat, dairy products, and high-fat fruits. Many polyunsaturated fatty acids can be found in most fats, whereas certain nutritionally-important subtypes are mostly found in oily fishes such as salmon or herring (FAO 2010).

Several authoritative dietary guidelines recommend that total fat intake should contribute less than 30% of daily energy intake in adults, and that saturated fats should be limited to less than 10% of total energy intake (Eckel 2014; FAO 2010; FAO/WHO 2015; Lichtenstein 2006; NDA 2010; US Department of Agriculture 2010). Hence, when reducing the total fat intake, the share of saturated fat should be lowered respectively. A recent systematic review (Harika 2013), however, reported that in the majority of the countries for which data were available (28 out of 45 countries), average total fat intake was above the recommended 30% energy threshold. The average proportion of energy contributed by total fats ranged from 11.1% (in Bangladesh) to 46.2% (in Greece). Moreover, for 29 countries the average saturated fat intake was larger than the recommended 10% of total energy intake (ranging from 2.9% (Bangladesh) to 20.9% (Indonesia) across all reported countries). Only a few of the included studies reported data on the distribution of fat intake within a population. Notably, the share of the population with an intake above the recommended threshold varied widely between countries (e.g. approximately 95% of the Danish population has a saturated fat intake of more than 10% energy, versus only 17% of the Indian population). In particular, for LMICs the share of total fat and saturated fat intake is predicted to increase as countries develop economically and socially and, therefore, an increased intake will become a component of diets across the globe (Popkin 2012; Wolmarans 2009).

Fat consumption and preventing obesity or other adverse health outcomes

The role of dietary fat intake in the worldwide rise in obesity is heavily debated. In particular two major issues stand out (Bray 1998): (i) can a decrease in overall fat intake lead to a decrease of overweight and obesity, and (ii) can the increase of overweight and obesity in LMICs be halted or slowed by preventing the progression towards a higher-fat diet. A recently published Cochrane systematic review (commissioned by the WHO Nutrition Guidance Expert Advisory Group (NUGAG) as part of the process of updating the guidelines on fat intake) investigated the relationship between total fat intake and obesity (Hooper 2015b). This review excluded studies that recruited populations specifically for weight loss and interventions intended to result in weight loss. Such studies are likely to be confounded by the implicit aim of reducing calorie intake and, hence, may over-represent studies with obese populations from Western countries. This would limit the transferability to non-obese populations or countries. Based on a metaanalysis of the included RCTs, the review authors concluded that consuming a lower proportion of total energy from fat results in small reductions in body weight (mean difference -1.54 kg, 95% confidence interval (CI) -1.97 to -1.12 kg), waist circumference (mean difference -0.30 cm, 95% CI -0.58 to -0.02 cm), and BMI (mean difference -0.50, 95% CI -0.74 to -0.26) among adults. Moreover, there was no suggestion of harms that might mitigate any benefits of weight loss. The authors recommend that for populations where the mean total fat intake is below 30% of energy consumed, such as in many LMICs, staying below this threshold may help to avoid obesity. For populations where mean total fat intake is above the 30% energy threshold, a reduction in intake below this threshold may support the maintenance of healthy weights (Hooper 2015b). The consumption of saturated fat has long been suspected to increase the risk and incidence of CHD (Keys 1950). However, the precise relationship is still being debated. A recent Cochrane review investigated the relationship between saturated fat intake and CVD (Hooper 2015a) and identified a robust effect on reducing combined cardiovascular events but not a general effect on all-cause mortality or cardiovascular mortality. Regarding the association between the intake of saturated fat and type 2 diabetes, a FAO expert group from their review of the literature concluded that there is a possible positive relationship (FAO 2010) but a recent review solely based on observational studies did not identify such an association (Souza 2015). One recommended alternative to reducing the total fat content of foods by lowering the total amount of saturated fat in them, is replacing saturated fat with polyunsaturated fat, as some of the latter fats may have a beneficial health effect. Saturated fats are most commonly found in processed or energy-dense, nutrient-poor food. The Cochrane review suggests that replacing saturated fat with polyunsaturated fat leads to a reduction in cardiovascular events (27% less), but this is not the case for other types of replacement (e.g. protein or monounsaturated fats) (Hooper 2015a). Similarly, a recent Cochrane review investigating the effect of increasing or decreasing amounts of a certain type of polyunsaturated fat (Omega 6) did not find evidence of any beneficial or harmful effects (Al-Khudairy 2015). Therefore, reducing the share of total energy coming from fat will have beneficial effects, while current evidence suggests that this should be predominantly achieved through a reduction in the content of saturated fat.

Description of the intervention

Taxation as a fiscal measure is usually designed to raise revenue for government expenditure. Taxation on commodities, however, has also been used to influence consumer behavior, e.g. taxation of foreign goods to discourage imports by making them more expensive, and to protect domestic producers. Similarly, taxation has been used to generally disincentivise consumption (and production). For example, many countries are considering or already have introduced 'sin taxes' on alcohol and tobacco to prevent alcohol

and tobacco use, often with the primary aim of preventing or reducing resultant public health harms (Blecher 2015).

Current evidence on the health effects of the different types of dietary fats - as outlined above, and reflected in several dietary guidelines (Eckel 2014; FAO 2010; FAO/WHO 2015; Lichtenstein 2006; NDA 2010; US Department of Agriculture 2010) - suggests that a tax on fat content should be designed in such a way that it may reduce the overall fat content by replacing unhealthy fats, e.g. saturated fat. We will include all types of taxation targeting fat contents in general but will pay special attention if and how less desirable dietary fats, in particular saturated fats, are being affected by the intervention.

Taxation to curb the content of fat in food is usually achieved through indirect taxes, implemented either as a sales or an excise tax (Sassi 2010). While producers or sellers pay the tax to the government, they are usually expected to shift the tax burden to the consumer by raising the price of the good in question. A sales tax is usually added to the price of a product at the point of sale. Value added tax (VAT; a special form of sales tax that is very common in many European countries) avoids a taxation cascade when a product has to go through a number of intermediaries by only taxing the valued added by a producer/reseller, i.e. value added equals sales price minus prices for input. The level of a sales tax can differ by type of commodity. For example, the UK has three different rates of VAT (standard: 20%, reduced: 5%, zero: no tax). Introducing a (higher) tax on a targeted product, e.g. foods high in saturated fat, may only require reassigning the product to a different category (Mytton 2007). A disadvantage of sales taxes/ VAT, however, is that the tax is on the price and not on the volume of the product (Bonnet 2013). As larger volumes of a product are usually cheaper in relative terms than smaller volumes, the impact of a sales tax could be reduced by increasing package size. Excise taxes, on the other hand, are usually levied as a fixed rate per unitvolume of content, independent of price or value. Hence, an excise tax may be more able to reduce the incentives for consumers to buy larger volumes of the taxed product, or switch to cheaper brands with virtually identical fat content.

How the intervention might work

Standard economic theory predicts that a price increase leads to a reduction in consumption. This finding, measured through elasticities, has been well established, not least for health-relevant commodities such as tobacco and alcohol (Lhachimi 2012). However, it is not always clear to what extent a tax will eventually increase retail prices. Although indirect taxes are assumed to be shifted to the consumer, examples exist where producers and retailers avoided doing this fully, illustrated by calls for minimum unit pricing of alcohol as a complement to taxation (Katikireddi 2014). In addition to increasing prices paid by the consumer as a consequence of the tax, producers may broadly respond in two ways: first, taxing (excessive saturated) fat content may lead to altered produc-

tion processes resulting in lower saturated fat content in absolute terms, by that also reducing total fat and the overall calorie content; and, second, producers may replace the share of saturated fat with other fats or nutrients, or both. Hence, the new calorie content may now be higher, lower, or unchanged. Moreover, these new ingredients may or may not have further health implications of their own. The first case is in line with the intention of such a tax and is expected to have overall beneficial health outcomes. In the second case, however, the effects of the changed food item on obesity and overall health are unclear. Similarly, the consumer may respond to tax-induced price increases with substitution, i.e. consuming a different product. Again, the effect of this substitution on energy intake and health outcomes is uncertain (Miao 2013) and the precise nature of the substitution may strongly depend on cultural, geographical, and social factors. Price is only one determinant among other environmental, social and cultural factors that influence consumption behavior and individual diet (Dixon 2013). Lastly, the manner by which the intervention is introduced and implemented may impact on its effectiveness. For example, taxation introduced primarily for revenue-raising purposes may not be set at a high enough level to influence behavior or may not have an impact on awareness of the adverse health consequences of the product.

A recent prominent example of a tax on saturated fat was a tax implemented in Denmark in 2011 (and repealed at the end of 2012) (Vallgarda 2015). It was imposed only on certain food types including meat, full-fat dairy products, animal fats, edible oils, and

margarine, and exempted food items with a saturated fat content of 2.3% or less. The tax was an excise tax and the rate was set at 16 Danish krone (approximate USD 2.90) per kilogram of saturated fat contained in the food item (Jensen 2015). Several publications investigated the effect of this tax. Jensen 2015 showed that the tax had an insignificant or small negative effect on the price of low- and medium-fat varieties of foods, but led to a 13% to 16% price increase for high-fat varieties of minced beef and cream products. Moreover, the tax induced substitution effects in consumers. A second publication showed that the tax led to a (modest) reduction in the share of energy from saturated fat, of 0.3% energy (Bødker 2015). Past potential examples of taxes on saturated fat took place in Mauritius and Norway which both used reportedly "fiscal measures" to increase prices for food items high in saturated fat (Dowse 1995; Norum 1997).

In Figure 1, we present a logic model showing the hypothesised causal pathways between taxation of total fat/saturated fat and obesity/other health outcomes. We anticipate that the introduction of a tax on saturated fat/total fat may influence prices or composition of food items, or both. The change in prices and/or composition of food items may affect buying behavior and, in turn, food consumption. Through a change in composition and/or substitution, the new diet may result in lower, higher, or unaltered energy intake. Similarly, the intake of total fat, saturated fat, and other nutrients will be influenced. These expected changes may have beneficial effects on obesity and/or other health outcomes.

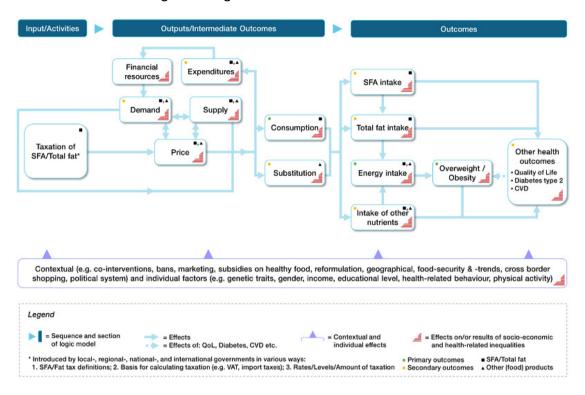


Figure 1. Logical model for taxation of saturated fat

Moreover, taxing a good depending on nutritional content sends a strong signal from the government to consumers and producers alike: the government is seriously concerned and is taking tangible measures to curb consumption (Sassi 2016). For example, even if the current level of taxation is low, once legislation for a tax is in place, it becomes much easier to increase the tax level in the future and the process of introducing a tax may raise awareness of the adverse health effects and facilitate behavioral change.

Why it is important to do this review

The World Health Assembly and the WHO in their global strategy on diet, physical activity and health stated that prices influence consumption choices and that public policies can influence prices through taxation, in ways that encourage healthy eating (Waxman 2004; WHO 2014). Moreover, taxes are considered highly cost-effective public health actions as they may raise revenue that outstrips implementation cost (Sassi 2014). This clearly demonstrates the importance of tax interventions for public health.

The expected health effect of a tax on fat has been repeatedly suggested and analysed in simulation studies for several countries (Jørgensen 2013; Nnoaham 2009; Thiele 2010; Tiffin 2011). Previous systematic reviews investigated taxes on foods linked to obesity in general and also included simulation studies (e.g. Eyles 2012; Maniadakis 2013; Thow 2014). However, a systematic re-

view of empirical evidence on the effect of taxing fat is lacking, despite existing examples of taxes on fat or saturated fat.

This research will be part of a set of reviews of different types of food taxes carried out by the same author group and sharing the same methodological approach. Our reviews will focus on the effects of governmental taxation on (i) fat content of processed or packaged food (this review), (ii) sugar-sweetened beverages (Heise 2016), and (iii) unprocessed sugar or sugar-added foods (Pfinder 2016).

OBJECTIVES

To assess the effects of taxation of fat content in food on consumption of total fat and saturated fat, energy intake, overweight, obesity, and other adverse health outcomes in the general population.

METHODS

Criteria for considering studies for this review

Types of studies

We expect the relevant evidence to be comprised of heterogeneous study designs. Beside small field studies, individual or cluster randomisation are likely to be impossible for evaluations of taxation interventions at a national level (Wansink 2014). Similarly, blinding is all but impossible in the evaluation of national level interventions.

We will therefore consider evidence from various sources for this review with respect to the quality of the study design, and adapt an approach previously used in at least two other Cochrane reviews in order to summarise 'best available evidence' (Gruen 2004; Turley 2013). This approach clearly separates studies into two broad categories: (1) studies meeting rigorous Cochrane Effective Practice and Organisation of Care (EPOC) criteria, and (2) supporting studies - those not meeting EPOC criteria, and having a higher risk of bias.

First, for the synthesis of main results, in line with EPOC criteria we will include:

- randomised controlled trials (RCTs);
- cluster randomised controlled trials (cRCTs);
- non-randomised controlled trials (nRCTs);
- controlled before-after (CBA) studies; and
- interrupted time series (ITS) studies.

According to EPOC, CBA studies require more than one intervention or control site, and ITS studies require a clearly-defined intervention time and at least three data points before and three after the intervention (EPOC 2013).

There will be no restriction in terms of publication date, language (CPH 2011), or study duration. Applications of taxes on saturated fat or total fat at a national level might feature a longer time lag between intervention and outcomes, especially for health outcomes, particularly as consumers might start stockpiling in expectation of a tax being applied (Jensen 2015).

We will exclude simulation studies, due to their potential limitations provoked by their basic assumptions (e.g. lack of potential supply-side changes, static models to predict weight loss), and other methodological restrictions (e.g. the use of a combination of heterogeneous data sources) (Lin 2011; Shemilt 2015).

Supporting studies

We will include as supporting studies:

- studies using an RCT, cRCT, nRCT, CBA, or ITS design but not fulfilling the EPOC criteria;
 - prospective cohort studies;
 - retrospective/non-concurrent cohort studies;
 - repeated cross-sectional studies; and
 - uncontrolled before-after (UBA) studies.

Supporting studies will not be included in the statistical synthesis of the primary included studies (i.e. those meeting EPOC criteria (EPOC 2013)) but will be synthesised narratively in addition to

the main findings. We will extract the same type of data from these supporting studies as we do for the included studies and will document these in a separate 'Characteristics of supporting studies' table. We will carry out 'Risk of bias' assessments on these studies, and undertake quality assessment, utilising the GRADE approach. We will present the findings from these supporting studies separately, as supplemental information in the results section and in separate 'Summary of findings' tables. Observations of similarities and/or differences of findings from the included studies and the supporting studies will be made in the 'Discussion' section, to help summarise the breadth, quality and the findings of the totality of research on the effects of these interventions.

The supporting studies may support or challenge results in the main findings and highlight uncertainty and potential research gaps. We will consider known limitations of UBA, cohort, and repeated cross-sectional studies for inclusion of studies, especially confounding and/or time trends. If UBA, cohort, and repeated cross-sectional studies are likely to be biased and do not use appropriate analytic strategies (e.g. stratification) or other designs (e.g. regression discontinuity) to control for known confounders and/or time trends, we will consider excluding these studies as 'supporting studies'.

Types of participants

We will include studies irrespective of participants' gender and age (children: 0 to 17 years, and adults: 18 years and over) from any country and setting.

We will exclude studies investigating the effects of taxing total fat or saturated fat focusing on specific subgroups, particularly:

- people receiving pharmaceutical intervention;
- people undergoing a surgical intervention;
- pregnant females;
- professional athletes;
- ill people who are overweight or obese as a side-effect, such as those with thyroiditis and depression; and
 - people with chronic illness(es);

at baseline and at the post-intervention phase due to higher or lower health risks compared to the general population.

Types of interventions

This review will include studies that evaluate the effects of taxes on fat contents in foods. Such a tax can be expressed as sales, or excise, or special VAT on the final product or an intermediary product (Chriqui 2008; Chriqui 2013; Jou 2012; Mytton 2012). Taxation maybe calculated either as a share of the food's weight, or as a share of the food's energy. Current evidence on health effects suggests that predominantly the content of saturated fats should be reduced. Therefore it is anticipated that the tax is designed to incentivise reductions in the amount of total or saturated fat in a food item, or at least to incentivise replacement of saturated fat

with other types of fat. The tax must be applied both for imports and domestically-produced food items. We explicitly exclude import taxes that only target selected food items that are high in fat as this is usually not being done to curb consumption of fats in general but to promote other, domestically-produced high fat products (e.g. butter) (Meershoek 1984). We will include interventional studies of taxation at any taxation level, provided for any duration, and studies that evaluate effects of artificial price increases of high saturated fat food that mimic taxation in clearlydefined environments (e.g. cafeterias, supermarkets, and vending machines) (Epstein 2012). Interventions can be at the local, regional, national, and multinational levels or field scenarios that imitate taxation effects. We will include studies with any control intervention, such as no intervention, as well as other food taxes, bans, minimum pricing, media campaigns, or subsidies on healthy foods (Jou 2012; Thow 2011).

Types of outcome measures

Our outcome selection and grouping was guided by preliminary evidence as discussed in the Background, on the basis of the logic model (Figure 1), and after feedback from the review advisory board members (see Table 1). Detailed information on advisory group involvement for this review is provided below. Primary outcomes include intermediate non-health related outcomes directly affected by tax-induced changes in food prices. As a result, consumption and energy intake may directly alter the primary health outcomes of overweight and obesity. Secondary outcomes will focus on food patterns (substitution and diet), expenditures, and other health outcomes directly or indirectly influenced by taxation of total fat/saturated fat content. We included demand as a proxy for consumption (see How the intervention might work).

Primary outcomes

The review will include changes from baseline to post-intervention in the following primary outcomes:

Consumption

- consumption of saturated fat (e.g. frequency, amount);
- consumption of total fat (e.g. frequency, amount);

Energy intake

- energy intake through saturated fat;
- · energy intake through total fat;
- total energy intake;

Overweight and obesity

- incidence of overweight and obesity; and
- prevalence of overweight and obesity.

All primary outcomes can be measured by physicians and other professionals or self-reported. Overweight and obesity can be measured by different anthropometric body mass indices, e.g. body weight, BMI, skinfold thickness, waist circumference (WC), waist-

to-hip ratio (WHR), and waist-to-height ratio (WHtR), bioelectrical impedance analysis (BIA), magnetic resonance imaging (MRI), isotope dilution analysis (IDA), ultrasound and computed tomography (CT) (WHO 2000). We will report changes in body mass indices if no data are available on the incidence or prevalence of overweight and obesity.

Secondary outcomes

The review will include changes from baseline to post-intervention in the following secondary outcomes:

Substitution and diet

• composition of diet (expressed as food groups or ingredients e.g. sugar, salt, fats);

Expenditures

- total expenditures on food;
- total expenditures on processed or packaged food containing fat or saturated fat;

Demand

 total sales of processed or packaged food containing fat or saturated fat;

Other health outcomes

- health-related quality of life (e.g. Short Form 36 (SF-36), Health-Related Quality of Life (HRQOL-14));
 - mortality; and
- any other health outcomes (e.g. type 2 diabetes, cardiovascular diseases).

All secondary outcomes can be measured by physicians and other professionals or self-reported.

Search methods for identification of studies

Electronic searches

We will search the following bibliographic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) via *Cochrane Library* (1948 to present);
- Cochrane Database of Systematic Reviews (CDSR) via *Cochrane Library* (1995 to present);
- MEDLINE via OvidSP (1946 to present);
- Embase via OvidSP (1947 to present);
- PsycINFO via OvidSP (1887 to present);
- Current Contents Medicine Database of German and

German-language journals (CC MED) via LIVIVO (2000 to present);

- LILACS via BIREME/VHL (1982 to present);
- EconLit via EBSCO (1969 to present);
- Campbell Library via Campbell Collaboration (2004 to present);

- Food Science and Technology Abstracts (FSTA) via OvidSP (1969 to present);
 - CINAHL via EBSCO (1937 to present); and
- Web of Science (SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI, CCR-EXPANDED, IC) via Thomson Reuters (1900 to present).

We will apply a search strategy with additional keywords for possible comparators (e.g. "subsidy") and we will not use filters for study types, in order to maximise the sensitivity of the literature search (Higgins 2011a, chapter 6.4.4). The search strategy for the MEDLINE database is presented in Appendix 1. We will modify this strategy to fit the syntax of the other databases. We will not include African Index Medicus (AIM) - a valuable resource for literature from low- and middle-income countries (LMICs) - in our review as a sensitive preliminary search with intervention key words (e.g. tax, taxation etc.) resulted in no hits.

Searching other resources

We will search the following electronic grey literature databases:

- ProQuest Dissertations & Theses Database (PQDT) via ProQuest;
- System for Information on Grey Literature in Europe (OpenGrey) via INIST/CNRS;
- Directory of Open Access Repositories (OpenDOAR) via CRC;
 - EconPapers via ORU;
- Social Science Research Network (SSRN eLibrary) via SSRN: and
- National Bureau of Economic Research (NBER) via NBER.

We will search the following databases using keywords relevant to the intervention (e.g. taxation, pricing), for completed or ongoing studies:

- WHO's International Clinical Trials Registry Platform (WHO ICTRP) (which includes references of the Clinical Trials.gov database) (http://www.who.int/ictrp); and
- Trials Register of Promoting Health Interventions (TRoPHI) (https://eppi.ioe.ac.uk).

Internet search engine

The first 30 hits in Google Scholar will be screened. We will use a set of terms from our searches of the academic and grey literature databases.

Targeted internet searching of key organisational websites

We will search the websites of major organisations and institutions, specifically:

- World Obesity Federation (www.worldobesity.org);
- The Obesity Society (www.obesity.org);

- Organisation for Economic Co-operation and Development (OECD) (www.oecd.org);
- World Health Organization (including regional web sites) (www.who.int; filter: "all sites");
- European Commission (ec.europa.eu/index en.htm);
- DG SANTE (ec.europa.eu/dgs/health*food-safety/index*en.htm);
 - Centers for Disease Control and Prevention (www.cdc.gov);
- National Institute for Health and Care Excellence (www.nice.org.uk);
 - World Trade Organization (www.wto.org); and
 - World Cancer Research Fund Institute (www.wcrf.org/).

Searching other resources

The reference lists of all records of all included studies will be searched by hand.

Advisory group

We have established a review advisory group (Higgins 2011a, chapter 2.3.4.3) of experts in the field of food taxation and health to comment and to give advice and suggestions based on the manuscripts of the reviews on taxation of sugar-sweetened beverages and unprocessed sugar. We provided the members of the review advisory group with detailed background information on those reviews. During the protocol stage, the group members were asked to provide feedback specifically on the focus and the relevance of this review's question, selected endpoints, study design, search strategy, database selection, and ongoing or unpublished studies. The review advisory group consists of researchers, academics, and policy makers. We received feedback via email and the online survey. All members of the advisory group are listed in Table 1.

Data collection and analysis

Selection of studies

An information specialist will conduct the database searches. If a reference or a full-text paper is not written in English, German, or French, the relevant content will be translated to English by using internet-based translators or we will ask for a translated version by contacting native speakers (e.g. colleagues from co-operating research institutes) or the corresponding author of the article. Screening will be conducted in six stages. First, titles of studies, and abstracts if available, will be reviewed by at least two authors independently. If an abstract is not provided by the database it originates from, and the title appears to be potentially relevant, we will progress the record to full-text review stage. Second, both authors will compare their list of relevant studies and in case of any

disagreement they will seek the opinion of a third author to achieve consensus. Third, full-text versions of potentially relevant studies will be retrieved or obtained. Fourth, the full-text versions will be screened by the two review authors independently. Fifth, each author will create a list of the studies that are considered to fulfil the inclusion criteria. Sixth, the two authors will compare their list with each other and in case of any disagreement the opinion of a third author will be decisive. Based on these six steps, studies will be selected for inclusion in the review (Higgins 2011a, chapter 7). We will present a flow chart based on PRISMA to depict the selection process (Moher 2009).

Data extraction and management

Data extraction will be performed independently by at least two authors and both authors will compare the extracted data. Disagreements will be resolved by a third author (Higgins 2011a, chapter 7.6.2). We will use a modified data extraction and assessment template from Cochrane Public Health (CPH) (CPH 2011). Prior to the main data extraction process, the authors will pilot the data extraction form to ensure standardised extraction. We will extract general information (publication type, country of study, funding source for study, potential conflict of interest), study eligibility (type of study, participants, type of intervention, duration of intervention, and type of outcome measures), study details (study aim, methods, results, intervention group, confounders, and confounder-adjusted and unadjusted outcomes), indicators of changes in food prices, and other relevant information (CPH 2011). Effect estimates for study populations based on PROGRESS categories (place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status (SES), social capital) will be extracted to evaluate impacts on equity. Other contextual factors (political system, co-interventions, reason for application, reason for certain tax level, intended beneficiaries, implementation costs, country- and region-specific level of gross domestic product (GDP), food security (availability, access, and use) and process evaluation criteria (e.g. satisfaction of participants, adherence)) that facilitate or hinder the application of the taxation on saturated fat will be extracted as well (Anderson 2011). Data will be entered into Review Manager 5 by one author. A second author will double-check the data entered (RevMan 2014).

Assessment of risk of bias in included studies

The risk of bias of every included study will be evaluated independently by at least two authors. In case of any disagreement, discrepancies will be discussed with a third author and resolved by consensus. Based on the template provided by CPH, the risk of bias of RCTs, nRCTs, CBA and ITS studies will be assessed using the Cochrane Effective Practice and Organisation of Care (EPOC) Group's guidance (CPH 2011), based on the Cochrane 'Risk of bias' tool. Both tools examine the following biases: selection, performance, detection, attrition, reporting, and other (EPOC 2009;

Higgins 2011b). For interrupted time series (ITS) the EPOC 'Risk of bias' tool examines three further risks of bias: "Was the intervention independent of other changes?", "Was the shape of the intervention effect pre-specified?", and "Was the intervention unlikely to affect data collection?" (EPOC 2009). The risk of bias of supporting studies and non-randomised quantitative studies will be assessed with the Quality Assessment Tool for Quantitative Studies, developed by the Effective Public Health Practice Project (EPHPP) (EPHPP 2010).

To judge the risk of bias according to Cochrane's 'Risk of bias' assessment tool and the EPOC guidance, we will use the following categories: "low", "high", and "unclear" (e.g. information is lacking or the risk of bias is unclear; Higgins 2011a, chapter 8.6). To judge the risk of bias according to the Quality Assessment Tool for Quantitative Studies, we will use the following three categories: "strong", "moderate", and "weak" (EPHPP 2010). We will provide 'Risk of bias' tables for all included studies.

Measures of treatment effect

We will report the effects of the treatment on dichotomous outcomes as odds ratios (ORs), risk ratios (RRs) or risk differences (RDs). In accordance with the recommendations from CPH, RRs will be the preferred reported measure of treatment effect (CPH 2011). If RRs are not presented in the study, but data to calculate the RRs are provided, we will calculate them. This also applies for data suitable to calculate ORs (e.g. obesity prevalence). If data to calculate the RRs are not provided, we will contact the corresponding author of the study by email or phone to request the RRs or the data to calculate them. If we cannot obtain RRs, we will report the treatment effect from the study report.

We will express continuous data as mean differences (MDs) where applicable or as standardised mean differences (SMDs). Shorter ordinal data will be translated into dichotomous data (expressed as ORs, RRs or RDs) and longer ordinal data will be treated as continuous data (expressed as MDs or SMDs). It is unclear whether there is a cut-off point which is common across the studies and can be used for dichotomisation (Higgins 2011a, chapter 7). The cut-off point will be part of the sensitivity analysis. Count data and Poisson data will be expressed as rate ratios. Time-to-event data (survival data) will be translated into dichotomous data when appropriate, or into hazard ratios (HRs).

If feasible, we will report the adjusted treatment effect. If a study does not present adjusted treatment effect measures, we aim to adjust the treatment effect measures for baseline variables by conducting additional multivariate analyses as far as we have access to the data or by contacting the corresponding author of the study by email or phone to request the adjusted treatment effect measures. If studies present intention-to-treat effect estimates, then we will prioritise these over average causal treatment effect estimates (Higgins 2011a, chapter 9).

When the treatment effect is described in cost estimates as de-

rived from economic studies, we will convert the cost estimates to US dollars (USD) and the price year 2015 to compare cost estimates from different studies with each other. To convert cost estimates into USD, we will apply an international exchange rate based on Purchasing Power Parities (PPPs). To convert cost estimates to the year 2015, we will apply GDP deflators or implicit price deflators for GDP. PPP conversion rates and GDP deflator values will be derived from the International Monetary Fund in the World Economic Outlook Database (http://www.imf.org/external/data.htm) (Higgins 2011a, chapter 15).

Unit of analysis issues

We will collect data on studies irrespective of whether individuals or groups are allocated to an intervention or control group. The analysis will consider the level at which allocation occurred, e.g. cluster-RCTs, cross-over trials, and multiple observations (repeated observations on subjects, recurring events, multiple body parts, and multiple intervention groups) for the same outcome (Higgins 2011a, chapter 9.3.1). Limited by the quality of reported data, we will consider data from cross-over trials (e.g. by incorporating the study data similar to a parallel group trial) and studies with multiple observations (e.g. by defining different periods of follow-up) (Higgins 2011a, chapter 9.3.4; chapter 16.4.5).

If control for clustering is missing or insufficient and if individual-level data are not presented in the study, we will request individual-level data from the contact study author. If feasible, we will reduce the size of each trial to its 'effective sample size' in order to correct intervention effects of cluster-RCTs. The effective sample size of an intervention group is the original sample size divided by the 'design effect'. We will calculate the design effect by the formula 1 + (M - 1) ICC. M is the average cluster size and ICC is the intracluster correlation coefficient (Higgins 2011a, chapter 16.3.4).

For dichotomous data, both the total number of participants and the number of participants who experience the event will be divided by the same design effect. For continuous data, only the sample size will be reduced; means and standard deviations will remain unchanged (Higgins 2011a, chapter 16.3.4).

Dealing with missing data

We will request all missing information and data from principal study authors by email or phone. The following steps will be taken to deal with relevant missing data:

- contact the authors;
- screen the study and investigate important numerical data such as randomised individuals as well as intention-to-treat (ITT), as-treated and per-protocol (PP) populations;
- investigate attrition rates as part of the 'Risk of bias' assessment in terms of dropouts, losses to follow-up and withdrawals;
- critically appraise issues of missing data and imputation methods (e.g. last observation carried forward (LOCF));

- impute missing standard deviations if contacted authors do not respond (Higgins 2011a, chapter 16.1); and
- apply sensitivity analyses to estimate the impact of imputation on meta-analyses.

Data 'not missing at random' due to systematic loss to follow-up or systematic exclusion of individuals from studies will be requested from study authors (Higgins 2011a, chapter 16.1.2).

Assessment of heterogeneity

In the event of substantial heterogeneity (methodological heterogeneity, statistical heterogeneity or considerable differences in the type of study populations, interventions, comparisons, and outcomes (PICO heterogeneity)), we will not perform meta-analysis. Statistical heterogeneity will be detected through visual inspection of the forest plots and by using a standard Chi² test with a significance level of P < 0.1. The I² statistic will be applied to quantify inconsistency across studies and to assess the impact of heterogeneity on the meta-analysis. Potential reasons for heterogeneity will be examined by conducting theoretically-informed subgroup analyses (Higgins 2011a, chapter 9.5).

Methodological and PICO heterogeneity will be assessed through tabulation and seeking explanations for heterogeneity between study findings. We will consider potential sources of heterogeneity such as:

- study population;
- geographical intervention area and intervention setting (e.g. schools, workplace, supermarkets);
- intervention characteristics (tax definition, basis for taxation, level of taxation);
 - implementation level and duration;
 - comparisons;
 - co-interventions; and
 - outcomes.

Assessment of reporting biases

Reporting biases, including publication bias, time lag bias, multiple (duplicate) publication bias, location bias, citation bias, language bias, and outcome reporting bias, occur when the dissemination of research results depends on their magnitude and direction (Higgins 2011a, chapter 10). If we find ten or more studies of the same outcome, we will produce and assess funnel plots for study effects resulting from reporting biases. When testing asymmetry in funnel plots (small study effects), we will investigate whether the relationship between a measure of study size and the estimated intervention effect is asymmetrical (Higgins 2011a, chapter 10.4). Funnel plots will be drawn using Review Manager 5 (RevMan 2014).

Data synthesis

If two or more studies report the same outcome and are sufficiently homogenous conceptually, methodologically, and statistically, we will perform meta-analyses of these studies using Review Manager 5 (RevMan 2014). For dichotomous outcomes we will apply the Mantel-Haenszel method and for continuous outcomes we will apply the inverse variance method. For all analyses, the randomeffects method will be applied as we expect differences in the underlying effect sizes due to contextual and application differences (Higgins 2011a, chapter 9.5.4). If a study reports two or more measures for the same outcome, then we will report the measure that is most reported by the other included studies. If a study reports multiple follow-ups for the same outcome (e.g. six months during the intervention, one year during the intervention, and six months after the intervention), we will prioritise the longest follow-up during the intervention (e.g. one year during the intervention in the example given). Nevertheless, we will extract all follow-

First, we will structure narrative synthesis by outcome categories of this review. Second, within these categories we will make further separation according to intervention setting (i.e. field scenarios, evaluation of implemented fat taxes) and study design (e.g. RCT, cRCT, nRCT, CBA, and ITS etc.) or study quality (Ryan 2016). Study results with insufficient homogeneity will be synthesised narratively. In addition to reporting findings as text and tables, we may consider both harvest plots and effect direction plots to summarise data not suitable for meta-analyses. Harvest plots are graphical summaries of data (represented by multiple shaded or non-shaded bars with varying heights) and can be used to indicate effect directions across included studies with non-standardised effect estimates of outcomes (e.g. anthropometric measures). Similarly, effect direction plots can be used to visualise information on effect directions with more focus on direct comparisons across studies (Ogilvie 2008; Thomson 2013).

We will provide a 'Summary of findings' table containing the outcomes of greatest interest for decision makers. Therefore, we will include at least the following outcomes: consumption of total fat, consumption of saturated fat, total energy intake, composition of diet prevalence of overweight or obesity, and total sales. This preselected list is based on feedback from our advisory group and external reviewers. This table will include information on the outcomes, comparative risks, the relative effect, the number of participants, the number of studies included, the quality of evidence based on GRADE, and additional comments. If feasible, we will use the GRADEprofiler software to prepare the 'Summary of findings' table (GRADE 2013; GRADEpro; Higgins 2011a, chapter 11).

Results of data synthesis will also be mapped against our initial logic model, to refine the theory of change and to assess the credibility of the assumed causal pathways.

Subgroup analysis and investigation of heterogeneity

We will investigate the following subgroups for primary outcomes, where feasible:

- high-income countries versus middle- and low-income countries;
 - high-income groups versus middle- and low-income groups;
 - high-educated groups versus low-educated groups;
 - different levels of taxation;
 - single tax versus multiple taxes on fat content;
- tax on saturated fat alone versus tax on saturated fat accompanied by other fat taxes;
- tax on fat accompanied by other interventions (e.g. bans, minimum pricing, media campaigns, or subsidies of healthy foods);
 - different types of taxation (e.g. excise tax or VAT);
 - children versus adults;
 - BMI subgroups.

If data are available, we will perform subgroup analyses according to dimensions of disadvantage based on PROGRESS categories (e.g. place of residence, gender, education) (Anderson 2011). If feasible, we will investigate the statistical significance of differences in the treatment effect between subgroups using t-tests and Chi²

Sensitivity analysis

Sensitivity analyses will be performed to determine the robustness of our results by conducting separate meta-analyses and presenting harvest plots for the studies included in our review according to the following factors:

- studies at 'low risk of bias' compared to those at 'high risk of bias';
 - source of funding;
 - published studies versus unpublished studies;
 - intervention duration;
 - follow-up time;
 - objective measures compared to subjective measures;
 - study design;
 - cut-off points of the measures of the treatment effect; and
 - imputation of data.

Studies assessed with a high or unclear risk of bias with respect to incomplete outcome data and baseline differences will not be included in these analyses. For cRCTs with adequate data provided, we will perform intracluster correlation value sensitivity analysis. We will report findings of sensitivity analyses as a summary table (Higgins 2011a, chapter 9.7).

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ADDITIONAL TABLES

Table 1. Advisory group members

Name	Occupation
Cristina Cleghorn	Department of Public Health, University of Otago, Wellington, NZ
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Barry Popkin	Professor of Global Nutrition, University of North Carolina, Chapel Hill, US
Torben Jørgensen	Professor Department of Public Health University of Copenhagen, Copenhagen, DK

APPENDICES

Appendix I. MEDLINE search strategy

- 1. exp Taxes/
- 2. exp Government Programs/ec, lj [Economics, Legislation & Jurisprudence]
- 3. exp Health Policy/ec, lj [Economics, Legislation & Jurisprudence]
- 4. exp Food Dispensers, Automatic/ec, lj, sn [Economics, Legislation & Jurisprudence, Statistics & Numerical Data]
- 5. exp Health Promotion/ec, lj [Economics, Legislation & Jurisprudence]
- 6. exp Nutrition Policy/ec, lj [Economics, Legislation & Jurisprudence]
- 7. exp Public Health/ec, lj [Economics, Legislation & Jurisprudence]
- 8. "demand elasticity".tw.
- 9. "policy intervention*".tw.
- 10. "sales tax".tw.
- 11. "thin subsidies".tw.
- 12. "vending machine*".tw.
- 13. budget.tw.

^{*} Indicates the major publication for the study

- 14. excise.tw.
- 15. fiscal.tw.
- 16. levied.tw.
- 17. levy.tw.
- 18. price.tw.
- 19. priced.tw.
- 20. prices.tw.
- 21. pricing.tw.
- 22. subsidy.tw.
- 23. subsidies.tw.
- 24. tax.tw.
- 25. taxation.tw.
- 26. taxed.tw.
- 27. taxes.tw.
- 28. taxing.tw.
- 29. OR/1-28
- 30. exp Dietary Carbohydrates/
- 31. exp Dietary Sucrose/
- 32. exp High Fructose Corn Syrup/
- 33. "chewing gum".tw.
- 34. "dietary sucrose".tw.
- 35. (("energy dens*" or "high energy" or "high-energy" or "low energy" or chips) and (fat* or sugar* or sweet* or food or diet* or nutrition or overweight or drink* or beverage* or protein* or carbohydrate*)).tw.
- 36. "HED calori*".tw.
- 37. "HED-calori*".tw.
- 38. "highcalori* food*".tw.
- 39. "high calori* food*".tw.
- 40. "high-calori* food*".tw.
- 41. "lowcalori* food*".tw.
- 42. "low calori* food*".tw.
- 43. "low-calori* food*".tw.
- 44. "ice cream*".tw.
- 45. "unhealthy food*".tw.
- 46. bakery.tw.
- 47. biscuit*.tw.
- 48. cacao.tw.
- 49. cake*.tw.
- 50. calorie*.tw.
- 51. candy.tw.
- 52. candies.tw.
- 53. bonbon*.tw.
- 54. chocolate*.tw.
- 55. confectionar*.tw.
- 56. cookie*.tw.
- 57. isoglucose.tw.
- 58. jam.tw.
- 59. jelly.tw.
- 60. jellies.tw.
- 61. liquorice.tw.
- 62. macronutrient*.tw.
- 63. maltose.tw.
- 64. marmalade.tw.
- 65. marzipan.tw.

- 66. pastr*.tw.
- 67. sucrose.tw.
- 68. sugar.tw.
- 69. sugars.tw.
- 70. sugary.tw.
- 71. sweet*.tw.
- 72. exp Butter/
- 73. exp Dietary Fats/
- 74. exp Energy Intake/
- 75. exp Fast Foods/
- 76. exp Margarine/
- 77. exp Plant Oils/ec [Economics]
- 78. "fastfood*".tw.
- 79. "fast food*".tw.
- 80. "fast-food*".tw.
- 81. "fattening-food*".tw.
- 82. "fattening food*".tw.
- 83. "fried food*".tw.
- 84. (coconut OR cooking OR palm OR vegetable OR soya OR soybean OR rapeseed OR linseed OR sunflower OR sesame OR peanut OR groundnut OR copra OR babassu OR olive OR thistle ADJ Oil).tw.
- 85. "salty-snack*".tw.
- 86. "salty snack*".tw.
- 87. "snack food*".tw.
- 88. "snack-food*".tw.
- 89. "takeaway food*".tw.
- 90. "takeaway-food*".tw.
- 91. "take away food*".tw.
- 92. "take away-food*".tw.
- 93. "take-away food*".tw.
- 94. "take-away-food*".tw.
- 95. "whole milk".tw.
- 96. burger*.tw.
- 97. butter.tw.
- 98. cheese.tw.
- 99. cream.tw.
- 100. crisps.tw.
- 101. (egg AND (fat* or sugar* or sweet* or food or diet* or nutrition or overweight or drink* or beverage* or protein* or carbohydrate*)).tw.
- 102. (eggs AND (fat* or sugar* or sweet* or food or diet* or nutrition or overweight or drink* or beverage* or protein* or carbohydrate*)).tw.
- 103. (fat AND (Food* or diet* or nutrition or nutrient or eat* or meal* or oil* or carbohydrate* or protein* or obesety or obesey)).tw.
- 104. (fatty AND (Food* or diet* or nutrition or nutrient or eat* or meal* or oil* or carbohydrate* or protein* or obesity or obese)).tw.
- 105. fats.tw.
- 106. fattening.tw.
- 107. fries.tw.
- 108. ghee.tw.
- 109. lard.tw.
- 110. margarine.tw.
- 111. mono-unsat*.tw.
- 112. monounsat*.tw.
- 113. omega3.tw.
- 114. "omega 3".tw.
- 115. omega-3.tw.

- 116. pizza.tw.
- 117. polyunsat*.tw.
- 118. poly-unsat*.tw.
- 119. sausage*.tw.
- 120. suet.tw.
- 121. exp Carbonated Beverages/
- 122. exp Food Preferences/
- 123. exp Food Habits/
- 124. "caloric-drink*".tw.
- 125. "caloric drink*".tw.
- 126. "carbonated-beverage*".tw.
- 127. "carbonated beverage*".tw.
- 128. "carbonated-drink*".tw.
- 129. "carbonated drink*".tw.
- 130. "energy-drink*".tw.
- 131. "energy drink*".tw.
- 132. "fizzy-drink*".tw.
- 133. "fizzy drink*".tw.
- 134. "high-calori* drink*".tw.
- 135. "high calori* drink*".tw.
- 136. "soda pop".tw.
- 137. "soft-drink*".tw.
- 138. "soft drink*".tw.
- 139. "sport-drink*".tw.
- 140. "sport* drink*".tw.
- 141. "sport*-drink*".tw.
- 142. cola.tw.
- 143. soda.tw.
- 144. SSB*.tw.
- 145. syrup*.tw.
- 146. OR/30-145
- 147. 29 AND 146
- 148. (animals NOT (humans AND animals)).sh.
- 149. 147 NOT 148

CONTRIBUTIONS OF AUTHORS

Stefan K Lhachimi: conceived and initiated the review and drafted the protocol

Frank Pega: reviewed and contributed to the development of the draft protocol and search strategy

Thomas L Heise: contributed to all stages of the protocol development

Candida Fenton: search strategy development

Gerald Gartlehner: reviewed and contributed to the development of the draft protocol

Ursula Griebler: reviewed the draft protocol Isolde Sommer: reviewed the draft protocol

Manuela Pfinder: contributed to all stages of the protocol development

S Vittal Katikireddi: reviewed and contributed to the development of the draft protocol and search strategy

DECLARATIONS OF INTEREST

Stefan K Lhachimi: received reimbursement for travel costs for participating in May 2013 in a workshop organised by the University of Maastricht at Schiphol (Netherlands) which was funded unrestrictedly by Nutricia Advanced Medical Nutrition (NAMN).

Frank Pega: is a technical officer at the World Health Organization.

Thomas L Heise: nothing to declare.

Candida Fenton: nothing to declare.

Gerald Gartlehner: nothing to declare.

Ursula Griebler: nothing to declare.

Isolde Sommer: nothing to declare.

Manuela Pfinder: nothing to declare.

S Vittal Katikireddi: is a member of the steering group of Obesity Action Scotland, to whom he provides unpaid advice on the evidence base for public health actions to tackle obesity.

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External sources

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