

# INPLASY

## Umbrella Meta-analyses and a narrative review of financial and non-financial sources of bias in food and health research

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### ADMINISTRATIVE INFORMATION

**Support** - Costs of licences for software and protocol registration- from The Academy of Nutrition Sciences.

**Review Stage at time of this submission** - Formal screening of search results against eligibility criteria.

**Conflicts of interest** - Christine Williams (CW) is Emeritus Professor and not in receipt of public or private research funding; she received honoraria for acting as Chair of grant awarding panels for UKRI (Transforming Food Systems) and World Cancer Research Fund (WCRF Grant Panel; Diet, Lifestyle and Cancer); no honoraria as ongoing Chair of the Nominations Committee of the British Nutrition Foundation or as a Trustee of the Academy of Nutrition Sciences (ANS).

Philip Calder (PC) has acted as a consultant for a number of food and pharmaceutical companies. He is a Member of the Board of Directors of the European Food Information Council (EUFIC); is Chair of the ILSI Global Assembly; and is a member of the Council of the International Union of Nutritional Sciences. PC leads a FENS Presidential Activity and Task Force on "Improving standards in the science of nutrition" and leads a UKRI-funded Diet and Health Open Innovation Research Club Hub (grant number BB/X51231X/1).

**INPLASY registration number:** INPLASY202560089

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 June 2025 and was last updated on 7 February 2026.

### INTRODUCTION

**Review question / Objective** Our hypotheses for the two meta-analyses we will conduct is that findings and conclusions for relationships between specific foods and human health (obesity, body weight, BMI and changes, cardiovascular diseases, gut function) will be more favourable (positive or neutral effects on human health) for those studies funded by the food industry than those funded by non-industrial sources. A narrative review will also be conducted to examine whether and what types

of non-financial sources of bias are present in the nutrition research literature.

**Rationale** Previous systematic reviews (SR) and meta-analyses (MA) have been undertaken concerning adverse effects of sugar-sweetened beverages (SSB) and artificial sweeteners (AS) on human health. These need to be updated by a meta-analysis (MA1) to include: i) recent methods of statistical analysis, ii) standardisation of the use of Relative Risk (RR) as the single point estimate for the primary outcome (a more relevant estimate than OR or HR used in previous studies) and, iii)

incorporation of new data from RCT and mechanistic studies. A second meta-analysis (MA2) aims to investigate whether there is evidence of bias in studies of relationships between specific foods, diets and dietary supplements and human health. Although a small number of SRs of foods, diets and supplement studies have not shown evidence of bias related to funding source (industry), there remains a prevalent view in the scientific and popular media that research studies supported by the food industry are conflicted and subject to presumption of bias. There is currently insufficient evidence to support this conclusion. Using the same methodologies for MA1 and MA2 will allow us to compare outcomes for studies supported by a range of food, diet and supplement industries, which represent a more diverse sector from those of the SSB and AS industries and beverages.

A narrative review will investigate other sources of bias in nutrition and health. The review will consider four potential types of bias: i) misreporting or misrepresenting results and conclusions to favour the authors' views and hypotheses, ii) attribution of causality when the study design does not allow causal conclusions, iii) citation bias and, iv) publication bias and White Hat Bias (WHB).

**Condition being studied** Each of the studies will focus on a range conditions related to nutrition and health.

MA1 : obesity BMI, body weight, weight gain, metabolic health, diabetes and CHD, gut health.

MA2: chronic conditions linked with diet, including obesity BMI, body weight, weight gain, metabolic health, diabetes and CHD, gut health

Narrative review: specific types of non-financial bias in nutrition research, including studies of obesity and weight gain, use of fat-controlled and trans fat diets in cardiovascular diseases.

## METHODS

**Search strategy** Searches will be limited to studies published between 1995-2025. Independent searches will be conducted by two individuals with the final selection of articles made after discussion and agreement with CMW.

**Participant or population** Population studies will have been conducted using male and female adults, adolescents (age range 16-75) or children including term or pre-term infants (gut supplement studies only).

### Intervention

MA1 MA2

Classification of the source of funding (The exposure)

The source of funding (industry, non-industry or undisclosed) was defined and categorised in several ways by the authors of included studies (see below).

#### Industry-funded

Studies will be classified as industry-funded if they are: wholly or part-financed by for-profit companies; included donation of study products or other in-kind contributions by a for-profit company or included studies financed by mixed sources (for-profit and other sources). Some studies classified a study as having industry ties where an author had disclosures of interest related to industry links.

#### Non-industry funded

Studies will be classified as non-industry if: the study was financed with government (public) funding, funded by a foundation or a philanthropic organisation, or financed by an institution (university, research organisation or research hospital).

#### Other sources of funding.

Nondisclosure of funding, or the study did not specify the source of funding.

### Comparator

The comparator is the non-industry funded group. Studies will be classified as non-industry if: the study was financed with government (public) funding, funded by a foundation or a philanthropic organisation, or financed by an institution (university, research organisation or research hospital).

Where there is non-disclosure of funding, or the study did not specify the source of funding these studies will be classified as non-industry funded.

**Study designs to be included** The two meta analyses will be umbrella meta-reviews which to minimise bias will require analysis of the extent of duplication of citations across the primary studies of the selected SRs and MAs.

The Narrative review will consider four potential types of bias: i) misreporting or misrepresenting results and conclusions to favour the authors' views and hypotheses, ii) attribution of causality when the study design does not allow causal conclusions, iii) citation bias and, iv) publication bias and White Hat Bias (WHB).

Where there is non-disclosure of funding, or the study did not specify the source of funding these studies will be classified as non-industry funded.

**Eligibility criteria** Inclusion criteria for studies included in this review

Systematic and systemised reviews and meta-analyses of observational studies, RCTs and experimental (mechanistic) studies with outcomes related to human health outcomes (studies MA1 and MA2).

Industry-funded and non-industry-funded studies with results and conclusions that had been rated as favourable to the industry or unfavourable to the industry by the authors.

Industry-funded and non-industry-funded studies with numerical data that can be used to estimate Relative Risk values for meta-analyses to allow comparisons of outcomes related to human health according to funding source.

Studies in adults, adolescents or children.

Articles in English and with access to the full version of the article.

**Information sources** PubMed and Scopus electronic databases; trial registers ; contact with authors where required. A hand search of the systematic reviews and meta-analysis reference lists, as well as published reviews which referred to food industry funding bias or guidance on collaboration with the food industry in nutrition research, was performed to identify additional potentially eligible primary research publications not identified by the electronic search.

**Main outcome(s)** Outcomes – results and/or conclusions classification as favourable or unfavourable to the industry

Results:

A favourable outcome to the industry will be recorded if:

1) The outcome measure is related to an adverse effect on health (e.g. SSB consumption and significantly higher body weight or BMI), where the study outcome was a neutral or significantly smaller observed effect in the industry-funded than in the non-industry-funded group.

2) If the outcome measure is related to beneficial effects on health (e.g. wholegrain foods and reduced risk of cardiovascular disease and mortality), and where the study outcome is a significantly greater effect size for the proposed positive health outcome, in the industry-funded group than the non-industry-funded group.

**Additional outcome(s)** None.

**Data management** Data extraction and management

One reviewer extracted the data of included studies using a standardised form developed for this review:

- (1) General data: principal author, publication year, language, DOI, country and publication journal,
- (2) Characteristics of the study: study designs.
- (3) Participant characteristics: infant, child, adolescent or adult and number of participants.
- (4) Main outcomes, funding sources, COI, publication bias
- (5) Outcome for any quality assessments undertaken by the authors of included studies.

#### **Quality assessment / Risk of bias analysis**

Quality assessment/ROB of the SRs /MAs were recorded and compared for industry-funded vs non-industry funded studies.

**Strategy of data synthesis** Statistical analyses will be undertaken using MedCalc software (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>; 2024).

To test whether our hypothesis confirms more favourable findings for the industry-funded than the non-industry-funded studies, we will conduct a meta-analysis of pooled Relative Risk values for the proportion of favourable outcomes for industry-funded versus non-industry-funded studies. When estimates for Relative Risk are available from the original publication, these will be verified using our calculations before pooling them in the meta-analysis. When odds ratios (ORs) are used in a review, we will converted these values to Relative Risk using the author's numerical data. Relative Risk values are considered to give a more conservative and relevant estimate to describe the likelihood of more favourable findings, since OR is a ratio of two odds, whereas the Relative Risk is a ratio of two probabilities. In the meta-analysis, two models will be to calculate the weighted pooled Relative Risk estimates: the fixed and random effects models.

We will use the Mantel-Haenszel method for calculating Relative Risk under the fixed effects model. To estimate the random effects model, we will incorporate the heterogeneity statistic to calculate the summary Relative Risk under the random effects model of DerSimonian-Laird. In our study, the calculation of pooled single-point estimates of Relative Risk will be undertaken using both fixed and random models.

Publication bias will be detected using two analyses: Eggar's graphical test and Begg's rank test For both tests, when the (two-sided) P-value is low, <P0.05-this indicated publication bias.

**Subgroup analysis** None anticipated at this stage.

**Sensitivity analysis** Sensitivity analysis. To assess the robustness of the meta-analyses, we will undertake a sensitivity analysis, which involves

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running the meta-analyses twice to determine whether the removal of one or more studies from the meta-analysis alters the main findings. We will undertake a sensitivity analysis in cases where a study outcome shows high heterogeneity or where a study differed in design compared with the other studies included in the main findings.

**Citation overlap** Due to the nature of umbrella MAs there is risk of overlap of primary study citations for this type of study design. Where there are significant numbers of replicated citations there is risk of bias due to exaggeration of the statistical power in umbrella MAs. A citation matrix of all the primary studies reported will be used in the SSB/AS meta-analysis. We will use the Corrected Covered Area (CCA) index of Pieper et al 2020 to estimate the percentage citation overlap.

**Language restriction** We will use English records to undertake our search.

**Country(ies) involved** United Kingdom.

**Other relevant information** None

**Keywords** financial; bias; food-industry; nutrition; health.; non-financial; bias; nutrition; health.

**Dissemination plans** We will publish findings in a high-ranking journal. Via the Academy of Nutrition Sciences we will publish editorials in our house journal and undertake blogs on the outcomes of the research on the Academy website.

#### **Contributions of each author**

Author 1 - Christine Williams - Author 1 has developed the concept, design and planning for the main studies and a pilot search study; CW will oversee the search and selection process for the two meta-analyses; with PC, CW will undertake the statistical analyses and use methods to reduce statistical bias in the final versions of the manuscript.

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Author 2 - Philip Calder - Author 2 has contributed ideas, content and planning for the search strategy and overall study; he will undertake statistical analysis, interpretation and presentation of the data and provide ongoing critical assessment throughout the development of the final draft versions of manuscript

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