

PROSPERO
International prospective register of systematic reviews



UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

Please complete all mandatory fields below (marked with an asterisk *) and as many of the non-mandatory fields as you can then click *Submit* to submit your registration. You don't need to complete everything in one go, this record will appear in your *My PROSPERO* section of the web site and you can continue to edit it until you are ready to submit. Click *Show help* below or click on the icon to see guidance on completing each section.

This record cannot be edited because it has been rejected

1. * Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

The association of food industry ties with findings of studies examining the effect of dairy foods intake with cardiovascular disease and mortality: Systematic review and Meta-analysis: protocol registration:

2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3. * Anticipated or actual start date.

Give the date when the systematic review commenced, or is expected to commence.

01/09/2016

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

01/06/2019

5. * Stage of review at time of this submission.

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

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| Review stage | Started | Completed |
|---|---------|-----------|
| Preliminary searches | Yes | No |
| Piloting of the study selection process | Yes | No |
| Formal screening of search results against eligibility criteria | Yes | No |
| Data extraction | Yes | No |
| Risk of bias (quality) assessment | Yes | No |
| Data analysis | No | No |

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

6. * Named contact.

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Nicholas Chartres

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Mr Chartres

7. * Named contact email.

Give the electronic mail address of the named contact.

ngar0960@uni.sydney.edu.au

8. Named contact address

Give the full postal address for the named contact.

The University of Sydney, D17, the Hub, 6th Floor, Charles Perkins Centre| the University of Sydney | Nsw | 2006

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

02 8627 4328

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of Sydney

Organisation web address:

11. * Review team members and their organisational affiliations.

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Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country are now mandatory fields for each person.**

Mr Nicholas Chartres. University of Sydney
Dr Alice Fabbri. The University of Sydney
Agnes Lau. University of California
Dr Joanna Diong. The University of Sydney
Assistant/Associate Professor Joanne Mckenzie. Monash University
Professor Lisa Bero. The University of Sydney

12. * Funding sources/sponsors.

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

Nicholas Chartres is a scholarship recipient (James Milner PhD scholarship in Pharmacy) from the University of Sydney.

Grant number(s)

13. * Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country are now mandatory fields for each person.**

15. * Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

The objective of this study is to determine if the presence of food industry sponsorship in primary nutrition studies examining the association of dairy foods with cardiovascular outcomes is associated with effect sizes, statistical significance of results and/ or conclusions that are favorable to the sponsor. We will also determine whether primary nutrition studies assessing the association of dairy foods with cardiovascular outcomes with industry sponsorship differ in their risk of bias compared with studies with no or other sources of sponsorship.

16. * Searches.

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

We will search the following databases from 2000-March 2019: Ovid MEDLINE; CINAHL; PubMed;

Cochrane Library; and ScienceDirect. No language restrictions will be applied

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17. URL to search strategy.

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search strategy. Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/129659_STRATEGY_20190322.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. * Condition or domain being studied.

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

To determine whether industry sponsorship and/or study methods are associated with the results and/or conclusions of primary nutrition studies assessing the association of dairy foods and cardiovascular outcomes.

19. * Participants/population.

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

We will include primary research studies of any design that quantitatively examine the association of dairy foods with cardiovascular outcomes in healthy adults.

20. * Intervention(s), exposure(s).

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

- The study quantitatively measures the effects of dairy consumption in humans.
- The study evaluates the effectiveness, efficacy or harms of dairy consumption.
- The study compares dairy food to control OR dairy food to other foods OR different levels of dairy consumption
- The study evaluates cow, goat or sheep milk, yogurt, cheese or custard. We will include and use the studies definition of dairy it is broader than milk, yogurt, cheese or custard.
- The study evaluates skim, low or full fat dairy products
- The study evaluates the effect of nutrients, e.g calcium and vitamin D when consumed within a dairy product

21. * Comparator(s)/control.

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Dairy vs Dairy (different doses) Dairy vs Dairy (different fat content) Dairy vs No dairy Dairy vs Other food

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Other (mixed intervention)

22. * Types of study to be included.

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

RCTs, Controlled Trials, Cohort, Case-control, Pre/Post, Other/Various

23. Context.

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

• The study evaluates clinical outcomes (e.g. risk ratio/hazard ratio, etc.) and/or the surrogate outcomes of Blood Pressure (mmHg) mortality, nonfatal heart attack, stroke, etc.) and/or the surrogate outcomes of Blood Pressure (mmHg)

24. * Main outcome(s).

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

a. Primary Outcome 1 and 2

- o Statistical significance of results
- o Effect size of outcomes

For each study, the result reported for each primary outcome will be categorized as:

- (1) Favourable if the result are statistically significant ($p < 0.05$ or 95% confidence interval [CI] excluding no difference) and in the direction of dairy being more efficacious, less harmful or no more harmful than the comparator;
- (2) Unfavourable if the result was statistically significant (e.g. $P < 0.05$ or 95% confidence interval including the possibility of no difference) in the direction of the comparator being more efficacious or less harmful.

We will also extract the effect estimates for primary outcomes.

We will classify the results of the study as favourable if the stated primary outcome is reported as favourable.

If the study has multiple primary outcomes we will report the study as favourable if at least one of the outcomes is reported as favourable.

b. Primary Outcome 3 (Conclusions)

The conclusions reported in the published papers will be categorized as:

- (1) Favourable if the dairy intervention was preferred to comparator
- (2) Unfavourable if the comparator intervention was preferred to the test one OR if the test intervention

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showed a risk increase.

* Measures of effect

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

As this is not relevant to our study, we have nothing to include.

25. * Additional outcome(s).

List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

~~We used the QUOROM (Risk of Bias) tool for randomised studies (15) to measure the methodological quality of randomized controlled trials. The tool assesses bias across 7 domains and each of these will be reported separately. To measure methodological quality in observational studies we will use the ROBINS-I tool for non-randomized studies (ROBINS-I)(16), which also measures bias across 7 domains.~~

d. Secondary Outcome 2 (Concordance between results and conclusions)

We will classify concordance between study results and conclusions as 'yes' if the authors' conclusions are supported by all outcomes. This will include the reporting of all significant and non-significant results.

Otherwise, concordance will be classified as 'no'

* Measures of effect

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

As this is not relevant to our study, we have nothing to include.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Selection Process

Two investigators (NC & AF) will independently screen the titles and abstracts of all retrieved records for obvious exclusions. Two investigators (NC & AF) will then assess the remaining papers based on full text, applying the aforementioned inclusion criteria for included studies. Agreement will be reached on any discrepancies by consensus between the two assessors. If agreement cannot be reached, a third assessor (LB) will make a decision. The reasons for the eligible papers being excluded will be described in

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'Characteristics of excluded papers' table.

Data collection process

- a) Title of the paper
- b) Year of publication
- c) Study design
- d) Comparisons:
- e) Sample size of study
- f) Mean age of participants
- g) Intervention or observation period
- h) Definition of intervention and exposure
- i) Risk of Bias
- j) Primary Hypothesis of the study (Verbatim)
- k) Primary outcomes measures
- l) Conclusion
- m) Concordance between conclusions and results
- n) Industry Sponsorship
- o) Role of the Funder: Information about the role of the sponsor as stated in the study
- p) The institutional affiliation of the corresponding author will be obtained from the article and classified into the following categories
- q) Country of origin (verbatim)
- r) Author COI

27. * Risk of bias (quality) assessment.

Describe the method of assessing risk of bias or quality assessment. State which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

We will use the Cochrane Risk of Bias tool for randomised studies (15) to measure the methodological quality of randomized controlled trials. The tool assesses bias across 7 domains and each of these will be reported separately. To measure methodological quality in observational studies we will use the ROBINS-I tool for non-randomized studies (ROBINS-I)(16), which also measures bias across 7 domains.

28. * Strategy for data synthesis.

Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.

To test our hypothesis that studies with dairy industry sponsorship will be more likely to have favourable

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results, we will compare the risk of dairy industry sponsored studies having a favourable result with the risk of non-dairy industry funded studies having a favorable result. Using Rev Manager we will calculate the pooled risk ratio (RR) and its 95% confidence interval using the Mantel-Haenszel fixed-effect model. However, when substantial heterogeneity is observed, we will use an inverse variance DerSimonian-Laird random-effects model. We will assess heterogeneity using I^2 and use a random-effects model when statistical heterogeneity is substantial, defined as an I^2 50%.

To test our hypothesis that effect estimates will differ between studies with dairy industry sponsorship and those without sponsorship, we will compare the pooled effect estimates from dairy vs. non-dairy sponsored studies. We will pool the effect estimates of homogenous studies measuring dichotomous outcomes, (e.g. RR, HR, OR for all-cause mortality, CVD mortality, cardiovascular events, etc) calculating pooled risk ratios as described above. Blood pressure is a continuous outcome, so we will attempt to pool homogeneous studies and measure the mean difference from baseline measures.

To test our hypothesis that studies with dairy industry sponsorship would be more likely to have favourable conclusions we will compare the risk of dairy industry sponsored studies having favourable conclusions with the risk of non-dairy industry funded studies having a favorable conclusion. We will calculate the pooled risk ratio (RR) and its 95% confidence interval using the Mantel-Haenszel fixed-effect model. However, when substantial heterogeneity is observed, we will use an inverse variance DerSimonian-Laird random-effects model. We will assess heterogeneity using I^2 and use a random-effects model when statistical heterogeneity is substantial, defined as an I^2 50%.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach. We will conduct an a priori subgroup analysis on low fat and full fat dairy products to determine if studies measuring the effects of low fat products have different results from studies that measure full fat dairy products.

We will conduct an a priori subgroup analysis by the risks of bias of the included studies to determine if studies that have a high risk of bias have different results from studies that have a low risk of bias. We hypothesize that industry sponsored studies will have the same level of risk of bias as non-industry sponsored studies.

30. * Type and method of review.

Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

Type of review
Cost effectiveness

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No
Diagnostic
No
Epidemiologic
No
Individual patient data (IPD) meta-analysis
No
Intervention
No
Meta-analysis
Yes
Methodology
No
Narrative synthesis
No
Network meta-analysis
No
Pre-clinical
No
Prevention
No
Prognostic
No
Prospective meta-analysis (PMA)
No
Review of reviews
No
Service delivery
No
Synthesis of qualitative studies
No
Systematic review
Yes
Other
No

Health area of the review

Alcohol/substance misuse/abuse
No
Blood and immune system
No
Cancer
No
Cardiovascular
Yes
Care of the elderly
No
Child health
No
Complementary therapies

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No
Crime and justice
No
Dental
No
Digestive system
No
Ear, nose and throat
No
Education
No
Endocrine and metabolic disorders
No
Eye disorders
No
General interest
No
Genetics
No
Health inequalities/health equity
No
Infections and infestations
No
International development
No
Mental health and behavioural conditions
No
Musculoskeletal
No
Neurological
No
Nursing
No
Obstetrics and gynaecology
No
Oral health
No
Palliative care
No
Perioperative care
No
Physiotherapy
No
Pregnancy and childbirth
No
Public health (including social determinants of health)
Yes
Rehabilitation
No
Respiratory disorders
No

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Service delivery
No

Skin disorders
No

Social care
No

Surgery
No

Tropical Medicine
No

Urological
No

Wounds, injuries and accidents
No

Violence and abuse
No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.
English

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Australia

33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

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Do you intend to publish the review on completion?

Yes

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Nutrition, Industry Sponsorship, Conflict of Interest, Bias, Food Industry

37. Details of any existing review of the same topic by the same authors.

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

CRD42017055841 The association of industry sponsorship with outcomes of studies examining the effect of intake of wholegrain foods with cardiovascular disease and mortality: protocol

38. * Current review status.

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing.

Please provide anticipated publication date

Review_Ongoing

39. Any additional information.

Provide any other information the review team feel is relevant to the registration of the review.

40. Details of final report/publication(s).

This field should be left empty until details of the completed review are available.

Give the link to the published review.