PROSPERO International prospective register of systematic reviews

Review title and timescale

1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.
The association of industry sponsorship with outcomes of studies examining the effect of intake of wholegrain foods with cardiovascular disease and mortality: protocol

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.
28/11/2016

4 Anticipated completion date
Give the date by which the review is expected to be completed.
31/05/2017

5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started ×

Review stage	Started	Completed
Preliminary searches	No	Yes
Piloting of the study selection process	No	Yes
Formal screening of search results against eligibility criteria	No	Yes
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.

Review team details

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

7 Named contact email
Enter the electronic mail address of the named contact.
ngar0960@uni.sydney.edu.au

8 Named contact address
Enter 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
Enter the telephone number for the named contact, including international dialing 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.
THE UNIVERSITY OF SYDNEY

Website address:
sydney.edu.au

11 Review team members and their organisational affiliations

Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Mr	Nicholas	Chartres	The Hub, 6th floor, Charles Perkins Centre, The University of Sydney
Dr	Alice	Fabbri	The Hub, 6th floor, Charles Perkins Centre, The University of Sydney
Miss	Sally	McDonald	The Hub, 6th floor, Charles Perkins Centre, The University of Sydney
Miss	Jessica	Turton	The Hub, 6th floor, Charles Perkins Centre, The University of Sydney
Professor	Margaret	Allman-Farinelli	Charles Perkins Centre, The University of Sydney
Professor	Lisa	Bero	D17, The Hub, 6th floor, Charles Perkins Centre, 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. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.
Nicholas Chartres is a scholarship recipient (James Milner PhD scholarship in Pharmacy) from the University of Sydney. Alice Fabbri is a PhD student. She is recipient of a scholarship from the Italian Ministry of Education, Universities and Research. Sally McDonald is a scholarship recipient (Charles Perkins Centre summer scholarship) from the University of Sydney. Jessica Turton is a scholarship recipient (Charles Perkins Centre summer scholarship) from the University of Sydney.

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.
Are there any actual or potential conflicts of interest?
None known

14 Collaborators

Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details

Review methods

15 Review question(s)

State the question(s) to be addressed / review objectives. Please complete a separate box for each question.
The objective of this study is to determine if the presence of food industry sponsorship in primary nutrition studies examining the association of wholegrain 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 industry sponsored primary nutrition studies assessing the association of wholegrain foods with cardiovascular outcomes differ in their risk of bias compared with studies with no or other sources of sponsorship.

16 Searches

Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.
We will search the following databases from 1997-2016: Ovid MEDLINE; CINAHL; PubMed; PreMEDLINE; Cochrane Library; PsycINFO; Science Direct; and ERIC.

17 URL to search strategy
If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available
No

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.
public health - nutrition

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.
studies of adults and / or children were eligible for inclusion Inclusion Criteria • The study quantitatively measure the effects of wholegrain consumption in humans • The study involves or considers research with healthy children and/or adults with BMI 25% wholegrain, which may be whole, partially processed, ground or milled grain products in which every part of the grain is present in proportions that represent those present in the whole grain • The study has an outcome measure related to cardiovascular disease. • The study evaluates clinical outcomes (e.g. risk ratio/hazard ratio/odds ratio (RR/HR/OR) of cardiovascular mortality, nonfatal heart attack, stroke, etc.) and/or the surrogate outcomes of Blood Pressure (mmHg), LDL cholesterol, or HbA1c. • If the study examines mixed interventions (e.g. nutritional and educational) we will include them only if data related to wholegrain consumption are reported separately or can be obtained from the authors • In case of multiple reports from the same study, we will use the most complete and/or recently reported data Exclusion Criteria • Cross sectional studies, reviews and meta-analysis, commentaries. • The study examines dietary patterns only (e.g. the “Mediterranean diet”) • The study examines nutrients in an altered state (i.e. cereal fibre supplements or bran fortification) • The study examines total grain intake without differentiating between wholegrains and refined grains, or includes significant refined grain products in the wholegrain category. • The study examines only refined grain products, including cereal products containing high added fat or sugar (e.g. cakes, biscuits, pastries). • The study examines intake of supplemented or enriched foods (e.g. with the addition of bran) and not intake of wholegrain foods.

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).
Wholegrain vs Wholegrain (different doses) Wholegrain vs Wholegrain (different grains) Wholegrain vs no Wholegrain Wholegrain vs Refined grain Wholegrain vs Other food Other (mixed intervention)

22 Types of study to be included
Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.
Inclusion: RCT/ cluster RCT Controlled Trial/ pseudo-randomized Cohort Case-control Pre/Post Exclusion: Cross sectional studies reviews and meta-analysis commentaries.

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

24 Primary outcome(s)
Give the most important outcomes.
a. Primary Outcome 1 and 2 (Results and effect size) - Statistical significance of results - Effect size of outcomes b. Primary Outcome 3 (Conclusions) For this study, we will use clinical outcomes only for observational studies and both clinical and surrogate outcomes for interventional studies. We define as clinically relevant cardiovascular outcomes as mortality related to specific cardiovascular events, and/or number of cardiovascular events (including myocardial infarction, stroke). We define relevant surrogate outcomes as blood pressure (mmHg), lipid marker (LDL cholesterol),

or HbA1c. Our rationale for including only these outcomes is that these were used to measure cardiovascular disease risk factors in the development of the Australian Dietary Guidelines We will define favorable results and conclusions as those showing a statistically significant association of wholegrain consumption and decreased cardiovascular disease risk. For each study we will record the stated hypothesis for the study, including the stated outcomes to be measured. If primary outcomes are not stated we will take mortality (related to specific cardiovascular events) as the primary outcome to be measured. In the absence of mortality outcomes, we will take number of cardiovascular events (including non-fatal myocardial infarction and stroke) as the primary outcome. In the absence of these, blood pressure, LDL cholesterol, or HbA1C as risk factors will be used as the primary outcome.

Give information on timing and effect measures, as appropriate.
variable

25 Secondary outcomes

List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.
Secondary Outcome 1 (Methodological risk of bias) Secondary Outcome 2 (Concordance between results and conclusions) Risk of Bias Assessment We will use the Cochrane Risk of Bias tool for randomised studies 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-E tool for non-randomized studies (ROBINS-E), which also measures bias across 7 domains. 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’.

Give information on timing and effect measures, as appropriate.
variable

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