

BMJ Open Reporting completeness and outcomes of the diet- and nutrition-related systematic review planning process: protocol for a meta-epidemiological study

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ABSTRACT

Introduction Dietary recommendations should be based on scientific evidence, and ideally, systematic reviews (SRs) are conducted as part of the guideline development process. The usability of SRs for decision-making is primarily determined by the quality of the evidence from available primary studies, as well as the quality of the SRs themselves. A comprehensive SR protocol ensures high-quality implementation and minimises bias, while making these protocols publicly accessible, promotes transparency and prevents redundancy. The PROSPERO database offers valuable insights into planned methodologies. The aim of this study is to investigate the completeness of reporting in SR protocols for diet- or nutrition-related trials, determine how this has changed over time, and examine the publication of completed SRs by comparing their content with those described in the corresponding protocols.

Methods and analysis We developed a systematic search strategy for PROSPERO to identify nutrition- or diet-related SR protocols registered at two different time points (2019 and 2024). Following a screening process to identify eligible protocols, relevant predefined data will be extracted. Subsequently, a structured search will be conducted to identify potential journal publications of the selected protocols, as well as publications describing the results of the SRs, from which relevant predefined data will be also extracted. The methodology of the published articles will be compared with the corresponding a priori protocols registered in PROSPERO. The PROSPERO records registered in 2019 will be compared with those registered in 2024. The results will be evaluated by descriptive statistics, the reporting completeness of PROSPERO records will be assessed based on Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P), the planned use of any approaches to assess certainty of evidence will be investigated, and the adherence of published SRs to the methodological details outlined in their corresponding PROSPERO entries will be examined.

Ethics and dissemination Since both databases and publications used in this study are publicly available, ethical approval is not required. Results of the study will be submitted for publication in an international, peer-reviewed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study enables assessment of temporal differences in the completeness of PROSPERO-registered protocols.
- ⇒ The use of PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) allows for a standardised assessment of protocol completeness.
- ⇒ The present study considers exclusively those protocols of systematic reviews, which summarise primary studies with specific study design.
- ⇒ The findings of the study may be limited by the completeness and accuracy of data available in PROSPERO.

PROSPERO registration number The present study has previously been registered with the Open Science Framework (<https://osf.io/8fsx7>).

INTRODUCTION

“A systematic review attempts to collate all the empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimising bias, thus providing more reliable findings from which conclusions can be drawn and decisions made”.¹ SRs form a bridge between primary research and evidence-based decision-making in healthcare.² Evidence-based professional guidelines use SRs to answer questions based on available research results and facilitate informed decision-making regarding healthcare and public health policy for providers, patients, policymakers and other stakeholders.^{3–6}

The production of SRs that deviate from prespecified standards has the potential to bias healthcare decisions; therefore, the assessment of the quality of evidence is crucial, as stronger recommendations can be made with more robust evidence.^{7–9} In this regard,

the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was developed to assess the certainty of evidence and how confident we can be that the estimated effect in the trial is close to the true effect. The tool is utilised regularly by organisations such as the WHO, the National Institute of Health and Care Excellence, the Canadian Task Force for the Preventive Services, and the Cochrane Collaboration.¹⁰ Despite the great utility of the GRADE approach in assessing the certainty of the evidence of published trials, the quality of the planning process of SRs at a protocol stage is not always addressed. It is therefore recommended that a more in-depth investigation be conducted into the quality of SR protocols, to gain a more comprehensive insight. “A protocol is specifying in advance the scope and methods to be used by the review, to assist in planning and reduce the risk of bias in the review process”.¹¹

Dietary recommendations should be formulated based on scientific evidence; however, the quality of evidence is often low, because both observational studies and nutrition-related randomised controlled trials (RCTs) face several methodological challenges. These challenges include issues such as control groups, placebos, blinding, lack of a priori data analysis plans or post hoc transparency in data analyses, selective reporting of results, lack of study registration on public databases, lack of a replication culture and limited data sharing.^{12 13} These methodological limitations subsequently have an impact on SRs, compromising the reliability of the evidence and further complicating the work of guideline development groups.^{14 15}

SR protocols are essential for enhancing the quality of applied methodology.¹⁶ By making these protocols publicly available, potential biases resulting from predefined methods can be mitigated, thereby fostering transparency in research: verification of the adherence to the planned protocol is possible, redundancy can be prevented, and subsequent updates to SRs can be facilitated. Although the publication of protocols in the form of journal articles has increased in recent years, this practice is currently primarily observed in the case of Cochrane protocols, with many protocols remaining unpublished.^{17–19}

PROSPERO, a free, web-based repository maintained by the Centre for Reviews and Dissemination at the University of York and supported by the United Kingdom National Health Services, is the most widely used platform for researchers to publicly share SR protocols.^{20 21} It requires submissions in a format that adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, but while it provides valuable insight into planned methodologies, the records are not critically appraised and may lack necessary data for comparison with the completed SR.²² The PROSPERO system has undergone development in recent years and reached its current form in March 2025. The developments primarily affected the processing of registrations and the search function. Studies have shown that around

one-third of performed SRs deviate from the planned methods previously registered in the protocols, and many PROSPERO entries are not updated or accurately reflect the status of SRs.^{7 23–27} To optimise the use of PROSPERO, collaboration between authors of SRs, PROSPERO staff, journals and their editors is essential to enhance the currency and accuracy of the records.²⁵

The quality of SRs related to nutrition has not yet been extensively studied, with few studies in this area. Zajac and colleagues found, for example, that <10% of SRs on nutrition for cancer prevention had a preregistered protocol, and only half of them assessed risk of bias of primary studies.²⁸ Most SRs (97%) were of critically low quality, making them untrustworthy. Similarly, Matterné and colleagues found that nine out of twelve SRs on complementary feeding for allergy prevention in early childhood had high risk of bias and low quality.²⁹ These issues need to be considered when developing dietary guidelines.

It is currently unclear to what extent nutrition-related pre-registered SRs are published, to what extent published SRs adhere to predefined methodological standards, and how the certainty of evidence is assessed. Therefore, the present research aims to address these gaps by having the following objectives: (1) To assess and compare the completeness of reporting in PROSPERO registrations submitted in 2019 and 2024, (2) To investigate the planned use of any approaches used for certainty assessment, (3) To evaluate publication rates and time to publication for diet- or nutrition-related SRs and (4) To examine the adherence of published SRs to the methodological details outlined in their corresponding PROSPERO entries.

METHODS AND ANALYSIS

As a reporting checklist for methodological studies in health research is not yet published,³⁰ we follow the guidance of Mbuagbaw and colleagues when describing the planned methods for our meta-epidemiological study.³¹

The completeness of reporting and outcomes of the planning process for SRs of diet- or nutrition-related trials will be studied in 2 years, 2019 and 2024. The year 2019 was selected for analysis based on the average time to publication of SRs, thereby enabling a comparative analysis with the published SR.^{7 26 32} The year 2024 was selected to facilitate an examination of the latest protocols, thereby enabling a comparison of the protocols registered in these 2 years. In the case of records from 2019, the following aspects will be explored: the completeness of reporting in PROSPERO records, the use of any certainty assessment approaches, publication rates and time to publication, and the adherence of published SRs to corresponding PROSPERO entries. For records from 2024, only the completeness of reporting in the registered protocol and the use of any certainty assessment approaches will be examined. The screening process began in September 2025 and is ongoing, with

Table 1 Outcomes grouped by research objectives

Research objective	Outcome	Description
Completeness of reporting in PROSPERO registration	Adherence to PRISMA-P checklist	How many items adhere to the PRISMA-P checklist?
Certainty assessment	Confidence in cumulative evidence	Is the confidence in cumulative evidence reported? (Yes/No)
	Method	What method is used for certainty assessment?
Publication rate	Published protocol	Is there a published protocol available? (Yes/No)
	Published results	Is there a published SR available? (Yes/No)
	Time to publication	How many months elapsed between the first submission to PROSPERO and the first publication date as an SR (counted in months)?
	Timeliness of record status	Is the record status up to date? (Yes/No)
Adherence	Adherence per item	How adherent is SR to the protocol at the item level?
PRISMA-P, Preferred Reporting Items for Systematic review and Meta-Analysis Protocols; SR, systematic review.		

data extraction scheduled to commence in April 2026. The study is expected to be completed by June 2027.

Inclusion criteria

We will include SR protocols (1) Registered in PROSPERO in either 2019 or 2024, (2) Conducted in the field of nutrition or diet, (3) In any human population, without restrictions on age or health status and (4) Summarising RCTs, and/or non-randomised studies of interventions, including: quasi-randomised studies, controlled before-after studies, interrupted time series and cohort studies. Eligible interventions conducted in the field of nutrition or diet will include the following types: introduction of a special or new diet (eg, low or high energy, plant-based, ketogenic, sugar-free, etc), supplementation with a new food or ingredient (eg, herbs, vitamins, drinks/juices, etc), omission or reduction of certain foods, drinks, ingredients (eg, salt, sugar, gluten, caffeine, etc), changes in the food preparation process (eg, kitchen technological process, replacement of certain ingredients, proportion of ingredients), modifications in eating habits (eg, number of meals, conditions of eating, fasting/intermittent fasting, etc) and educational interventions related to nutrition or diet. Protocols encompassing multiple interventions will be included if the comparator allows

a clear assessment of the effect of nutrition alone (eg, intervention: specific diet+physical activity; comparator: physical activity). No restrictions will be imposed on the comparison. Cochrane and non-Cochrane SR protocols will be included, but Cochrane reviews will be handled separately.

Exclusion criteria

Protocols of SRs summarising non-human studies will be excluded. Protocols of non-interventional SRs, qualitative SRs, mixed-method SRs, updates of reviews, umbrella reviews and methodological studies will be excluded.

Search for protocols in PROSPERO

We employed a systematic search strategy, combining a pre-specified set of keywords and controlled vocabulary, to identify SR protocols related to nutrition or diet in PROSPERO. The search strategy for PROSPERO was developed based on the work of Durão and colleagues and is provided in online supplemental additional file 1.³³ We conducted a preliminary search in PROSPERO on 26 March 2025 to evaluate the efficacy of our search strategy. The final search was conducted on 24 June 2025.

Selection of eligible records

Screening of the identified protocols for the eligibility criteria will be carried out independently and in duplicate by two researchers using the SR software Covidence. Potential conflicts will be resolved by discussion. In the case of disagreement, a third study author will be consulted.

Data extraction from PROSPERO records

Data extraction will be carried out independently and in duplicate by two researchers in an excel sheet. In instances where multiple versions are available, data will be extracted from the first and last versions. The specific data to be extracted is detailed in online supplemental additional file 2. The data extraction sheet will be pilot tested on 10 included SR protocols to ensure consistency in the interpretation of data elements. If necessary, modifications will be applied.

Assessment of protocol publication and/or results publication

Once we have identified the PROSPERO records, we will search for their corresponding protocol publication and/or results publication. PubMed will be searched using the name of the first author, the last author, keywords from the title and PICO (Population, Intervention, Comparison, Outcome) elements. If no article is identified, we will repeat the search in Google Scholar and Google. This search process will be conducted independently by two authors.

If a published protocol is identified, the same data will be extracted as from the PROSPERO records. In addition, the date and the journal of publication will be extracted.

If a publication reporting the results of the study is identified, two researchers will extract data independently from each other and in duplicate. The specific data to be

extracted is detailed in online supplemental additional file 3. The data extraction sheet will be pilot tested on 10 included SRs to ensure consistency in the interpretation of data elements. If necessary, modifications will be applied. A study is considered to be fully published if it presents results from the SR and has been published in full text in a peer-reviewed journal. For those records that yielded more than one article, data from all articles will be extracted and compared with the protocol.

Subsequently, two authors will independently and in duplicate compare the methodology of the published articles with the corresponding prior protocols registered in PROSPERO.

Analyses and data synthesis

For PROSPERO entries in 2019, we will look at the following outcomes (table 1): (1) Completeness of reporting in PROSPERO registration, (2) Use of certainty assessment approaches, (3) Publication rates and (4) Adherence of published results to predefined protocol. For PROSPERO entries in 2024, we will look only at the outcomes (1) and (2). Each outcome will be evaluated and synthesised as follows:

1. To assess and compare the **completeness of reporting in PROSPERO registration** in 2019 and 2024: the assessment of reporting completeness will be conducted by examining the adherence of the protocol to the PRISMA-P checklist.³⁴ This will be achieved by assigning a score between zero and one to each of the 17 PRISMA-P items and subsequently summing up these scores. In instances where PRISMA-P items constitute a single variable, one point will be allocated if the response to the variable question is “yes” or “not applicable”, and zero points will be assigned if the response is “no”. In instances where composite PRISMA-P items comprise two or more sub-items, an approach is implemented that allocates equal credit to all sub-items. The ratio calculated by dividing the number of fulfilled sub-items and the total number of sub-items is assigned as a score to these composite PRISMA-P items. The total score will thus be 17 points, with higher scores indicating better PRISMA-P adherence. Descriptive statistics will be employed to show the overall quality of the protocols. The quality of the PROSPERO entries in 2019 and in 2024 will be compared using an independent-sample t-test (or Mann-Whitney U test).
2. To investigate the planned use of any **approaches to assess the certainty of evidence**: the protocol will be examined to ascertain whether there is a description of the methodology for evaluating the strength of the body of evidence (yes=1, no=0). A comparison will be made between the protocols in 2019 and 2024 using an independent-sample t-test (or Mann-Whitney U test). Furthermore, the different methods used for certainty assessment will be studied by descriptive statistics.
3. To evaluate the **publication rates** of diet or nutrition-related SRs: descriptive statistics will be employed to present the percentage of protocols that have been

published, the PROSPERO records that resulted in a published SR, the time to publication (counted in months from first submission in PROSPERO to first publication date), and the timeliness of record status.

4. To examine the **adherence** of published SRs to the methodological details outlined in their corresponding PROSPERO entries and published protocol (if applicable): a list has been prepared based on the PRISMA checklist to assess adherence. The list consists of the following items: objective, population, intervention, comparator, primary outcome, secondary outcome(s), databases (to be) searched, study design (to be) included, methods for risk of bias assessment, methods of data synthesis, methods for certainty assessment, analysis of subgroups, and information related to funding. The adherence of the items will be scored as 1=no match; 2=not mentioned in the protocol; 3=match in part; 4=no match, but stated in the results publication; 5=match. Adherence will be assessed at the item level using descriptive statistical methods. In the event of alterations in the protocol, the initial and final versions are examined to ascertain adherence to the published SR. The time elapsed between the date of the last change and the date of publication is examined.

ETHICS AND DISSEMINATION

As the planned study is based on data from publicly available sources, no ethical approval is required. The preliminary findings will be presented at relevant scientific conferences. The results of the study will be submitted for publication in an international, peer-reviewed journal.

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