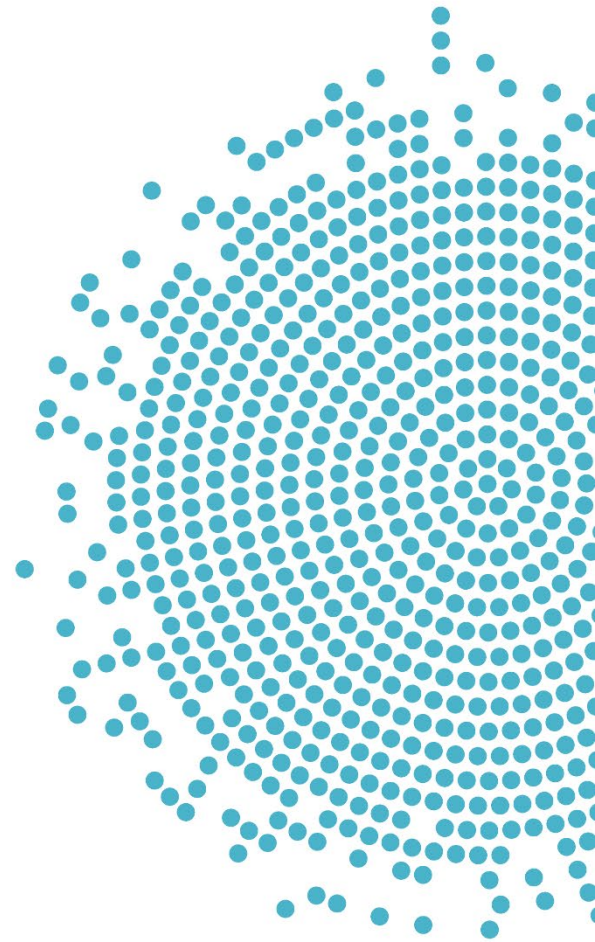


# Dietary Patterns and Risk of Cognitive Decline, Dementia, and Alzheimer's Disease: A Systematic Review Protocol

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# Table of contents

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<b>Table of contents</b> .....	<b>3</b>
<b>Introduction</b> .....	<b>4</b>
<b>Methods</b> .....	<b>5</b>
Develop a protocol .....	5
Develop an analytic framework .....	5
Develop inclusion and exclusion criteria .....	6
Search for and screen studies .....	9
Extract data and assess the risk of bias .....	9
Synthesize the evidence .....	9
Develop a conclusion statement and grade the evidence .....	9
Recommend future research .....	10
<b>Acknowledgments and funding</b> .....	<b>10</b>
<b>Appendix</b> .....	<b>11</b>
Table 1. Review history .....	4
Table 2. Protocol revisions .....	5
Table 3. Inclusion and exclusion criteria .....	7
Figure 1. Analytic framework for the systematic review question: What is the relationship between dietary patterns and risk of cognitive decline, dementia, and Alzheimer’s disease?.....	6

## Introduction

To prepare for the development of the *Dietary Guidelines for Americans, 2025-2030*, the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) identified a proposed list of scientific questions based on relevance, importance, potential federal impact, and avoiding duplication, which were posted for public comment.\* The Departments appointed the 2025 Dietary Guidelines Advisory Committee (Committee) in January 2023 to review evidence on the scientific questions. The proposed scientific questions were refined and prioritized by the Committee for consideration in their review of the evidence. Their review forms the basis of their independent, science-based advice and recommendations to HHS and USDA, which is considered as the Departments develop the next edition of the *Dietary Guidelines*. As part of that process, the following systematic review question has been identified: What is the relationship between dietary patterns consumed and risk of cognitive decline, dementia, and Alzheimer’s disease?

The Committee will conduct a systematic review to address this question, with support from USDA’s Nutrition Evidence Systematic Review (NESR) team. This question will update the systematic review conducted by 2015 Dietary Guidelines Advisory Committee (**Table 1**).

**Table 1. Review history**

Date	Description	Citation
February 2015	Original systematic review conducted by the 2015 Dietary Guidelines Advisory Committee published	2015 Dietary Guidelines Advisory Committee: Systematic Reviews of the Dietary Patterns, Foods and Nutrients, and Health Outcomes Subcommittee. February 2015. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://nesr.usda.gov/sites/default/files/2019-04/2015DGAC-SR-DietaryPatterns.pdf">https://nesr.usda.gov/sites/default/files/2019-04/2015DGAC-SR-DietaryPatterns.pdf</a>
October 2023	Systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Hoelscher DM, Anderson C, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Callahan E, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Cognitive Decline: A Systematic Review Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://nesr.usda.gov/protocols">https://nesr.usda.gov/protocols</a>
February 2024	Revisions to the systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Hoelscher DM, Anderson C, Booth S, Deierlein A, Fung T, Gardner C, Giovannucci E, Raynor H, Stanford FC, Talegawkar S, Taylor C, Tobias D, Obbagy J, Callahan E, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Risk of Cognitive Decline: A Systematic Review Protocol. May 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <a href="https://nesr.usda.gov/protocols">https://nesr.usda.gov/protocols</a>

\* Dietary Guidelines for Americans: Learn About the Process. 2022. Available at: <https://www.dietaryguidelines.gov/work-under-way/learn-about-process>

# Methods

The NESR methodology manual <sup>\*</sup> has a detailed description of the NESR methodology as it will be applied in the systematic reviews for the Dietary Guidelines for Americans, 2025-2030 Project. This section presents an overview of the specific methods that will be used to by the Committee to answer the systematic review question: What is the relationship between dietary patterns and risk of cognitive decline?

This systematic review updates an existing NESR systematic review completed by the 2015 Dietary Guidelines Advisory Committee,<sup>†</sup> which included evidence published from January 1980 to January 2014. This updated systematic review will synthesize the studies from the existing review with eligible studies published since January 1980 as one body of evidence, according to the methods described below.

## Develop a protocol

A systematic review protocol is the plan for how NESR’s methodology will be used to conduct a specific systematic review and is established by the Committee, *a priori*, before any evidence is reviewed. The protocol is designed to capture the most appropriate and relevant body of evidence to answer the systematic review question. Development of the protocol involves discussion of the strengths and limitations of various methodological approaches relevant to the question, which then inform subsequent steps of the systematic review process. The protocol describes all of the methods that will be used throughout the systematic review process. Additionally, the protocol includes the following components, which are tailored to each systematic review question: the analytic framework, the inclusion and exclusion criteria, and the synthesis plan. When updating an existing review, the Committee uses the analytic framework and the inclusion and exclusion criteria from the existing review and makes adjustments to the protocol, if necessary. Differences in the inclusion and exclusion criteria between existing and updated reviews are documented in **Appendix 1**.

The protocol for this systematic review was posted online (<https://nesr.usda.gov/protocols>) in May 2023. Revisions to the systematic review protocol were made during the review process. These revisions are documented in **Table 2**.

**Table 2. Protocol revisions**

Date	Protocol revision	Description
January 2024	Inclusion and exclusion criteria for publication date were updated to document that the review will include studies published through January 2024.	This revision was made to document the final publication date range covered by the literature search.

## Develop an analytic framework

An analytic framework visually represents the overall scope of the systematic review question and depicts the contributing elements that will be examined and evaluated. **Figure 1** is the analytic framework for the systematic review and shows that the intervention or exposure of interest is dietary patterns consumed by

<sup>\*</sup> USDA Nutrition Evidence Systematic Review Branch. USDA Nutrition Evidence Systematic Review: Methodology Manual. February 2023. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/methodology-overview>

<sup>†</sup> 2015 Dietary Guidelines Advisory Committee: Systematic Reviews of the Dietary Patterns, Foods and Nutrients, and Health Outcomes Subcommittee. February 2015. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/sites/default/files/2019-04/2015DGAC-SR-DietaryPatterns.pdf>

children, adolescents, adults, and older adults. The comparators are different dietary patterns or different levels of adherence to/consumption of the same dietary pattern. The outcomes are cognitive decline, mild cognitive impairment, dementia, and Alzheimer’s disease. The key confounders may impact the relationships of interest and are sex, age, physical activity, anthropometry, race and/or ethnicity, education, and socioeconomic position in all populations, alcohol intake and smoking in adults, older adults. Dietary patterns are defined as the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed.

**Figure 1. Analytic framework for the systematic review question: What is the relationship between dietary patterns and risk of cognitive decline, dementia, and Alzheimer’s disease?**

<i>Population</i>	<i>Intervention/exposure</i>	<i>Comparator</i>	<i>Outcome</i>	<i>Key confounders</i>
Children and adolescents (2 up to 19 years)	Consumption of a dietary pattern	Different dietary pattern(s)	In adults and older adults: <ul style="list-style-type: none"> <li>• Cognitive decline</li> <li>• Mild cognitive impairment</li> <li>• Dementia</li> <li>• Alzheimer’s disease</li> </ul>	<ul style="list-style-type: none"> <li>• Sex</li> <li>• Age</li> <li>• Physical activity</li> <li>• Anthropometry</li> <li>• Race and/or ethnicity</li> <li>• Socioeconomic position</li> <li>• Education</li> <li>• Smoking (adults, older adults)</li> <li>• Alcohol intake (adults, older adults)</li> </ul>
Adults and older adults (19 years and older)		Different adherence/ consumption levels to the same dietary pattern		

**Synthesis organization:**

- I. **Population:** Adults; Older Adults
  - a. **Outcome:** Cognitive decline, mild cognitive impairment, dementia, Alzheimer’s disease

**Key definitions:**

Dietary patterns: the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed.

## Develop inclusion and exclusion criteria

The inclusion and exclusion criteria provide an objective, consistent, and transparent framework for determining which articles to include in the systematic review (see **Table 3**). These criteria ensure that the most relevant and appropriate body of evidence is identified for the systematic review question, and that the evidence reviewed is:

- Applicable to the U.S. population of interest
- Relevant to Federal public health nutrition policies and programs
- Rigorous from a scientific perspective

**Table 3. Inclusion and exclusion criteria**

Category	Inclusion Criteria	Exclusion Criteria
Study design	<ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials*</li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul>	<ul style="list-style-type: none"> <li>• Uncontrolled trials†</li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Ecological studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> <li>• Modeling and simulation studies</li> <li>• Mendelian randomization studies</li> </ul>
Publication date	<ul style="list-style-type: none"> <li>• January 1980 – January 2024‡</li> </ul>	<ul style="list-style-type: none"> <li>• Before January 1980, after January 2024</li> </ul>
Population: Study participants	<ul style="list-style-type: none"> <li>• Human</li> </ul>	<ul style="list-style-type: none"> <li>• Non-human</li> </ul>
Population: Life stage	<ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Children and adolescents (2 up to 19 years)</li> <li>○ Adults and older adults (19 years and older)</li> </ul> </li> <li>• At outcome:                             <ul style="list-style-type: none"> <li>○ Adults and older adults (19 years and older)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• At intervention or exposure:                             <ul style="list-style-type: none"> <li>○ Infants and toddlers (birth up to 24 months)</li> <li>○ Individuals during pregnancy</li> <li>○ Individuals during postpartum</li> </ul> </li> <li>• At outcome:                             <ul style="list-style-type: none"> <li>○ Children and adolescents (2 up to 19 years)</li> </ul> </li> </ul>
Population: Health status	<ul style="list-style-type: none"> <li>• Studies that <u>exclusively</u> enroll participants not diagnosed with a disease§</li> <li>• Studies that enroll <u>some</u> participants:                             <ul style="list-style-type: none"> <li>○ diagnosed with a disease;</li> <li>○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>○ with the outcome of interest</li> <li>○ and/or hospitalized for an illness, injury, or surgery**</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Studies that <u>exclusively</u> enroll participants:                             <ul style="list-style-type: none"> <li>○ diagnosed with a disease;††</li> <li>○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>○ pre- or post-bariatric surgery;</li> <li>○ and/or hospitalized for an illness, injury, or surgery‡‡</li> </ul> </li> </ul>

\* Including quasi-experimental and controlled before-and-after studies

† Including uncontrolled before-and-after studies

‡ This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to January 2014.

§ Studies that enroll participants who are at risk for chronic disease will be included

\*\* Studies that exclusively enroll participants post-cesarean section will be included

†† Studies that exclusively enroll participants with obesity will be included

‡‡ Studies that exclusively enroll participants post-cesarean section will be included

Category	Inclusion Criteria	Exclusion Criteria
Intervention/ exposure	<ul style="list-style-type: none"> <li>Studies that examine consumption of and/or adherence to a dietary pattern [i.e., the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed], including, at a minimum, a description of the foods and beverages in the pattern of each intervention/exposure and comparator group                             <ul style="list-style-type: none"> <li>Dietary patterns may be measured or derived using a variety of approaches, such as adherence to <i>a priori</i> patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials</li> </ul> </li> <li>Multi-component intervention in which the isolated effect of the intervention of interest on the outcome(s) of interest is provided or can be determined</li> </ul>	<ul style="list-style-type: none"> <li>Studies that do not provide a description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern (i.e., studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed) in each intervention/exposure and comparator group</li> <li>Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is not analyzed or cannot be determined (e.g., due to multiple intervention components within groups)</li> </ul>
Comparator	<ul style="list-style-type: none"> <li>Consumption of and/or adherence to a different dietary pattern</li> <li>Different levels of consumption of and/or adherence to a dietary pattern</li> </ul>	<ul style="list-style-type: none"> <li>Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source is different between groups</li> </ul>
Outcome(s)	<ul style="list-style-type: none"> <li>Cognitive decline</li> <li>Mild cognitive impairment</li> <li>Dementia</li> <li>Alzheimer's disease</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Confounders	<ul style="list-style-type: none"> <li>Studies that control for at least one of the key confounders listed in the analytic framework</li> </ul>	<ul style="list-style-type: none"> <li>Studies that do not control for any of the key confounders listed in the analytic framework</li> </ul>
Study duration	<ul style="list-style-type: none"> <li>Intervention length <math>\geq 12</math> weeks</li> </ul>	<ul style="list-style-type: none"> <li>Intervention length <math>&lt; 12</math> weeks</li> </ul>
Size of study groups	<ul style="list-style-type: none"> <li>For intervention studies:                             <ul style="list-style-type: none"> <li><math>\geq 30</math> participants per study group for between-subject analyses,</li> <li>or a power calculation indicating that the study is appropriately powered for the outcome(s) of interest.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>For intervention studies:                             <ul style="list-style-type: none"> <li><math>&lt; 30</math> participants per study group for between-subject analyses,</li> <li>and no power calculation indicating that the study is appropriately powered for the outcome(s) of interest.</li> </ul> </li> </ul>
Publication status	<ul style="list-style-type: none"> <li>Peer-reviewed articles published in research journals</li> </ul>	<ul style="list-style-type: none"> <li>Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings</li> </ul>
Language	<ul style="list-style-type: none"> <li>Published in English</li> </ul>	<ul style="list-style-type: none"> <li>Not published in English</li> </ul>
Country*	<ul style="list-style-type: none"> <li>Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>	<ul style="list-style-type: none"> <li>Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>

\* The classification of countries on the Human Development Index (HDI) is based on the UN Development Program Human Development Report Office (<http://hdr.undp.org/en/data>) for the year the study intervention occurred or data were collected. If the study does not report the year(s) in which the intervention/exposure data were collected, the HDI classification for the year of publication is



## Search for and screen studies

NESR librarians, in collaboration with NESR analysts and the Committee, will use the analytic framework and inclusion and exclusion criteria to develop a comprehensive literature search strategy. The literature search strategy will include selecting and searching the appropriate bibliographic databases, translating search using syntax appropriate for the databases being searched, and employing search refinements, such as search filters. The full literature search will be available upon request, and will be fully documented in the final review.

The results of all electronic database searches, after removal of duplicates, will be screened independently by two NESR analysts using a step-wise process by reviewing titles, abstracts, and full-texts to determine which articles meet the inclusion criteria. Manual searching will be conducted to find peer-reviewed published articles not identified through the electronic database search. These articles will also be screened independently by two NESR analysts at the abstract and full-text levels.

## Extract data and assess the risk of bias

NESR analysts will extract all essential data from each included article to describe key characteristics of the available evidence, such as the author, publication year, cohort/trial name, study design, population life stage at intervention/exposure and outcome, intervention/exposure and outcome assessment methods, and outcomes. One NESR analyst will extract the data and a second NESR analyst will review the extracted data for accuracy. Each article included in the systematic review will undergo a formal risk of bias assessment, with two NESR analysts independently completing the risk of bias assessment using the tool that is appropriate for the study design.\*†‡ For review updates, data extraction and risk of bias assessment will be updated.

## Synthesize the evidence

The Committee will describe, compare, and combine the evidence from all included studies to answer the systematic review question. Synthesis of the body of evidence will involve identifying overarching themes or key concepts from the findings, identifying and explaining similarities and differences between studies, and determining whether certain factors impact the relationships being examined. The first level of synthesis organization will be by population including adults and older adults. Then, within each of the population groups, the evidence will be organized by similarity in outcome. Depending on the available evidence, the synthesis may be organized by participant characteristics such as race/ethnicity, socioeconomic position, and health status.

## Develop a conclusion statement and grade the evidence

After the Committee synthesizes the body of evidence, they will draft a conclusion statement or conclusion statements. A conclusion statement is one or more summary statements carefully constructed to answer the systematic review question. It reflects the evidence reviewed, as outlined in the analytic framework (e.g., PICO elements) and synthesis plan, and does not take evidence from other sources into consideration. The

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applied. Studies conducted prior to 1990 are classified based on 1990 HDI classifications. If the year is more recent than the available HDI values, then the most recent HDI classifications are used. If a country is not listed in the HDI, then the current country classification from the World Bank is used (The World Bank Country and Lending Groups, available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>)

\* Sterne JAC, Savovic J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. Aug 28 2019;366:I4898.doi:10.1136/bmj.I4898

† Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. Oct 12 2016;355:i4919.doi:10.1136/bmj.i4919

‡ ROBINS-E Development Group., Higgins J, Morgan R, et al. Bias In Non-randomized Studies - of Exposure (ROBINS-E). 2022. <https://www.riskofbias.info/welcome/robins-e-tool>

Committee will review, discuss, and revise the conclusion statement until they reach agreement on wording that accurately reflect the body of evidence.

The Committee will then assign a grade to each conclusion statement (i.e., strong, moderate, limited, or grade not assignable). The grade communicates the strength of the evidence supporting a specific conclusion statement to decision makers and stakeholders. NESR has predefined criteria, based on five grading elements that the Committee will use to evaluate and grade the strength of the evidence supporting each conclusion statement. The five grading elements are: consistency, precision, risk of bias, directness and generalizability of the evidence. Study design will also be considered during the grading process.

## Recommend future research

The Committee will identify and document research gaps and methodological limitations throughout the systematic review process. These gaps and limitations will be used to develop research recommendations that describe the research, data, and methodological advances that are needed to strengthen the body of evidence on a particular topic. Rationales for the necessity of additional or stronger research may also be provided with the research recommendations.

## Acknowledgments and funding

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The Committee members are involved in: establishing all aspects of the protocol, which presents the plan for how they are planning to examine the scientific evidence, including the inclusion and exclusion criteria; reviewing all studies that meet the criteria the Committee sets; deliberating on the body of evidence for each question; and writing and grading the conclusion statements. The NESR team, with assistance from Federal staff from HHS and USDA (Jean Altman, MS; Kara Beckman, PhD; Dana DeSilva, PhD, RD; Kevin Kuczynski, MS, RD; TusaRebecca Pannucci, PhD, MPH, RD; Julia Quam, MSPH, RND; Elizabeth Rahavi, RD) and Project Leadership (HHS: Janet de Jesus, MS, RD; USDA: Eve Stody, PhD), supports the Committee by facilitating, executing, and documenting the work necessary to ensure the reviews are completed in accordance with NESR methodology. Contractor support was also provided by Panum Telecom (Emily Madan, PhD; Verena McClain, MSc).

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# Appendix

## Appendix 1: Inclusion and exclusion criteria comparison between existing\* and updated systematic reviews for the research question: What is the relationship between dietary patterns and risk of cognitive decline?

Category	Existing Review	Updated Review	Change and Rationale
Study design	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials (including quasi-experimental and controlled before and after studies)</li> <li>• Quasi-experimental studies (i.e., prospective cohort studies)</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Nested case-control studies</li> <li>• Case-control studies</li> <li>• Uncontrolled trials</li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Uncontrolled before-and-after studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Randomized controlled trials</li> <li>• Non-randomized controlled trials<sup>†</sup></li> <li>• Prospective cohort studies</li> <li>• Retrospective cohort studies</li> <li>• Nested case-control studies</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Uncontrolled trials<sup>‡</sup></li> <li>• Case-control studies</li> <li>• Cross-sectional studies</li> <li>• Ecological studies</li> <li>• Narrative reviews</li> <li>• Systematic reviews</li> <li>• Meta-analyses</li> <li>• Modeling and simulation studies</li> <li>• Mendelian randomization studies</li> </ul>	Study design criteria were modified to enable focus on a stronger body of evidence and to align with current NESR standards.

\* 2015 Dietary Guidelines Advisory Committee: Systematic Reviews of the Dietary Patterns, Foods and Nutrients, and Health Outcomes Subcommittee. February 2015. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://nesr.usda.gov/sites/default/files/2019-04/2015DGAC-SR-DietaryPatterns.pdf>

<sup>†</sup> Including quasi-experimental and controlled before-and-after studies

<sup>‡</sup> Including uncontrolled before-and-after studies

Category	Existing Review	Updated Review	Change and Rationale
Publication date	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>January 1980-January 2014</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Before January 1980</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>January 1980- January 2024*</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Before January 1980, after January 2024</li> </ul>	End of the date range is updated to extend from the end of search in the existing review to present
Population: Study participants	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Human</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Non-human</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Human</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Non-human</li> </ul>	No change
Population: Life stage	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>At intervention/exposure and outcome:                             <ul style="list-style-type: none"> <li>Children, adolescents, adults, and older adults aged 2 years and older</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>At intervention/exposure and outcome:                             <ul style="list-style-type: none"> <li>Infants and toddlers (birth up to 24 months)</li> </ul> </li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>At intervention/exposure:                             <ul style="list-style-type: none"> <li>Children and adolescents (2 up to 19 years)</li> <li>Adults and older adults (19 years and older)</li> </ul> </li> <li>At outcome:                             <ul style="list-style-type: none"> <li>Adults and older adults (19 years and older)</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>At intervention/exposure and outcome:                             <ul style="list-style-type: none"> <li>Infants and toddlers (birth up to 24 months)</li> <li>Individuals during pregnancy</li> <li>Individuals during postpartum</li> </ul> </li> <li>At outcome:                             <ul style="list-style-type: none"> <li>Children and adolescents (2 up to 19 years)</li> <li>Individuals during pregnancy</li> </ul> </li> </ul>	Population life stage was narrowed to focus on the most relevant populations of interest

\* This review update date range encompasses the original systematic review date range, which included articles published from January 1980 to January 2014

Category	Existing Review	Updated Review	Change and Rationale
Population: Health Status	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Subjects who were healthy or at elevated chronic disease risk</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Low-calorie intervention (defined as &lt;1,600 kcal/day for women and &lt;2,000 kcal/day for men)</li> <li>Subjects who were hospitalized, diagnosed with disease, and/or receiving medical treatment</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies that <u>exclusively</u> enroll participants not diagnosed with a disease*</li> <li>Studies that enroll <u>some</u> participants:                             <ul style="list-style-type: none"> <li>diagnosed with a disease;</li> <li>and/or hospitalized for an illness, injury, or surgery</li> <li>with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>and/or with the outcome of interest</li> </ul> </li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Interventions designed to induce weight loss or treat overweight and obesity through energy-restriction/hypocaloric diets for the purposes of treating additional or other medical conditions</li> <li>Studies that <u>exclusively</u> enroll participants:                             <ul style="list-style-type: none"> <li>diagnosed with a disease;†</li> <li>hospitalized for an illness, injury, or surgery;‡</li> <li>with severe undernutrition, failure to thrive/underweight, stunting, or wasting;</li> <li>and/or with the outcome of interest</li> </ul> </li> </ul>	No change other than to clarify intent

\* Studies that enroll participants who are at risk for chronic disease will be included

† Studies that exclusively enroll participants with obesity will be included

‡ Studies that exclusively enroll participants post-cesarean section will be included

Category	Existing Review	Updated Review	Change and Rationale
Intervention/exposure	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• A description of the dietary pattern(s) consumed by subjects (i.e., the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed), including, at a minimum, a description of the foods and beverages in the pattern)</li> <li>• Dietary patterns may be measured or derived using a variety of approaches, such as adherence to a priori patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials.</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Studies that do not provide a description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern (i.e., studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed).</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>• Studies that examine consumption of and/or adherence to a dietary pattern [i.e., the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed], including, at a minimum, a description of the foods and beverages in the pattern of each intervention/exposure and comparator group                             <ul style="list-style-type: none"> <li>○ Dietary patterns may be measured or derived using a variety of approaches, such as adherence to a <i>priori</i> patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials</li> </ul> </li> <li>• Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>• Studies that do not provide a description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern (i.e., studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed in each intervention/exposure and comparator group).</li> <li>• Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is not analyzed or cannot be determined (e.g., due to multiple intervention components within groups).</li> </ul>	<p>Revisions were made to clarify the intent of the intervention/exposure and comparator criteria, but do not represent a change in how the criteria were applied</p>

Category	Existing Review	Updated Review	Change and Rationale
Comparator	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Adherence to a different dietary pattern</li> <li>Different levels of adherence to a dietary pattern</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Consumption of and/or adherence to a different dietary pattern</li> <li>Different levels of consumption and/or adherence to a dietary pattern</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source is different between groups</li> </ul>	No change other than to clarify the intent
Outcome(s)	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Dementia</li> <li>Cognitive impairment</li> <li>Alzheimer's disease</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Cognitive decline</li> <li>Mild cognitive impairment</li> <li>Dementia</li> <li>Alzheimer's disease</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	No change other than to clarify outcomes
Confounders	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>n/a</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>n/a</li> </ul>	<p><u>Included:</u></p> <ul style="list-style-type: none"> <li>Studies that control for one or more of the key confounders listed in the analytic framework</li> </ul> <p><u>Excluded:</u></p> <ul style="list-style-type: none"> <li>Studies that do not control for any of the key confounders listed in the analytic framework</li> </ul>	Criteria were added to enable focus on a stronger body of evidence
Study duration (not applied to pregnancy and postpartum studies)	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Intervention length ≥12 weeks</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Intervention length &lt;12 weeks</li> </ul>	Study duration criteria were modified to enable focus on a stronger body of evidence

Category	Existing Review	Updated Review	Change and Rationale
Publication status	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Peer-reviewed articles published in research journals</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Peer-reviewed articles published in research journals</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings</li> </ul>	No change
Language	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Published in English</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Not published in English</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Published in English</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Not published in English</li> </ul>	No change
Country*	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Subject populations from countries with high or very high human development, according to the 2011 Human Development Index</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as medium or low on the 2011 Human Development Index.</li> </ul>	<p><u>Included</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul> <p><u>Excluded</u></p> <ul style="list-style-type: none"> <li>Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected</li> </ul>	NESR now applies the Human Development Index classification from the year in which the intervention/exposure data were collected

\* In order to determine the inclusion exclusion criteria for country, the Human Development classification was used. This classification is based on the Human Development Index (HDI) ranking from the year the study intervention occurred or data were collected (UN Development Program. HDI 1990-2017 HDRO calculations based on data from UNDESA (2017a), UNESCO Institute for Statistics (2018), United Nations Statistics Division (2018b), World Bank (2018b), Barro and Lee (2016) and IMF (2018). Available from: <http://hdr.undp.org/en/data>). If the study did not report the year in which the intervention occurred or data were collected, the HDI classification for the year of publication was applied. HDI values are available from 1980, and then from 1990 to present. If a study was conducted prior to 1990, the HDI classification from 1990 was applied. If a study was conducted in 2018 or 2019, the most current HDI classification was applied. When a country was not included in the HDI ranking, the current country classification from the World Bank was used instead (The World Bank. World Bank country and lending groups. Available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-country-and-lending-groups>)