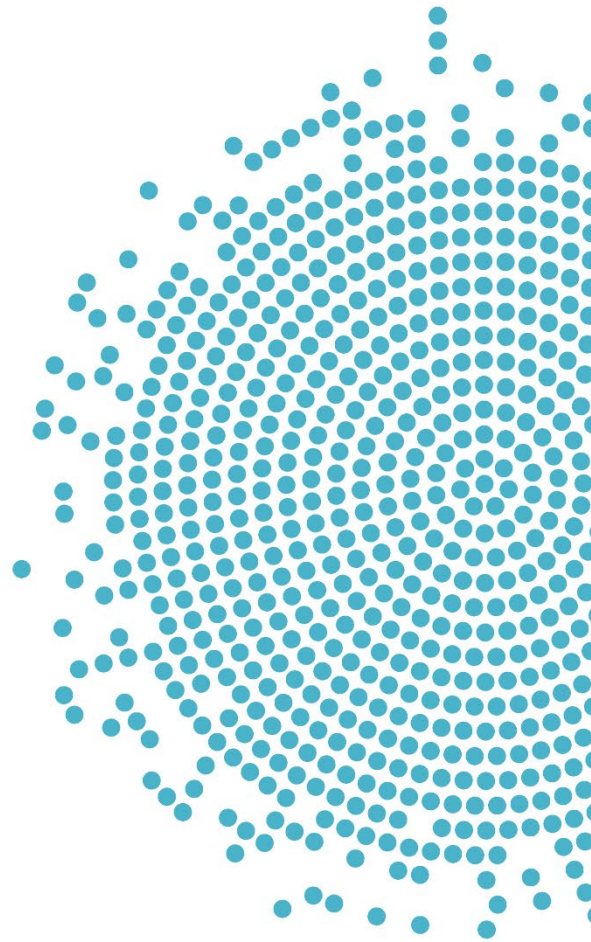




Dietary Patterns and Bone Health: A Systematic Review Protocol

Deanna M. Hoelscher, PhD, RDN, LD, CNS, FISBNPA,^{a,b} Cheryl A.M. Anderson, PhD, MPH, MS,^{a,c} Sarah Booth, PhD,^{a,d} Andrea Deierlein, PhD, MPH, MS,^{a,e} Teresa Fung, ScD, RD,^{a,f} Christopher Gardner, PhD,^{a,g} Edward Giovannucci,^{a,h} Hollie Raynor, PhD, RD, LDN,^{a,i} Fatima Cody Stanford, MD, MPH, MPA, MBA, FAAP, FACP, FAHA, FAMWA, FTOS,^{a,h} Sameera Talegawkar, PhD,^{a,j} Chris Taylor, PhD, RDN, LD, FAND,^{a,k} Deirdre Tobias, ScD,^{a,h} Julie Obbagy, PhD, RD,^l Emily H. Callahan, MS,^m Laural Kelly English, PhD,^m Amanda Fultz, PhD,^m Ramkripa Raghavan DrPH, MPH, MSc,^m Nicole Reigh, PhD,ⁿ Molly Higgins, MLIS,^o Gisela Butera, MEd, MLIS,^p Nancy Terry, MLIS^p



^a Dietary Patterns and Specific Dietary Pattern Components Across Life Stages Subcommittee, 2025 Dietary Guidelines Advisory Committee

^b UT Health Houston School of Public Health, Subcommittee Chair

^c University of California San Diego

^d Tufts University, Committee Chair

^e New York University

^f Simmons University

^g Stanford University

^h Harvard University

ⁱ University of Tennessee Knoxville

^j The George Washington University

^k The Ohio State University

^l Branch Chief, Nutrition Evidence Systematic Review (NESR) Branch; Nutrition Guidance and Analysis Division (NGAD), Center for Nutrition Policy and Promotion (CNPP), Food and Nutrition Service (FNS), U.S. Department of Agriculture (USDA)

^m Systematic Review Analyst, NESR Branch; NGAD, CNPP, FNS, USDA

ⁿ Systematic Review Analyst, Panum Telecom, under contract with FNS, USDA

^o Systematic Review Librarian, NESR Branch; NGAD, CNPP, FNS, USDA

^p Biomedical Librarian/Informationist, National Institutes of Health Library

Suggested citation: 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 EH, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Bone Health: 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: <https://nesr.usda.gov/protocols>

Related citation: Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetselaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Venkatramanan S, Butera G, Terry N, Obbagy J. Dietary Patterns and Bone Health: A Systematic Review. July 2020. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.DGAC2020.SR0105>

The contents of this document may be used and reprinted without permission. Endorsements by NESR, NGAD, CNPP, FNS, or USDA of derivative products developed from this work may not be stated or implied.

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons using assistive technology should be able to access information in this report. For further assistance please email SM.FN.NESR@USDA.gov.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotope, American Sign Language, etc.) should contact the responsible agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online at [How to File a Program Discrimination Complaint](#) and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by:

- (1) mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW, Washington, D.C. 20250-9410;
- (2) fax: (202) 690-7442; or
- (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

Table of contents

Table of contents	3
Introduction	4
Methods	5
Develop a protocol	5
Develop an analytic framework	5
Develop inclusion and exclusion criteria	7
Search for and screen studies	11
Extract data and assess the risk of bias	11
Synthesize the evidence	11
Develop [a] conclusion statement[s] and grade the evidence	11
Recommend future research	12
Acknowledgments and funding	12
Appendix	13
Table 1. Review history	4
Table 2. Inclusion and exclusion criteria.....	8
Figure 1. Analytic framework for the systematic review question: What is the relationship between dietary patterns consumed and bone health?.....	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 bone health? 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 the 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 in 2015	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
July 2020	Systematic review update by the 2020 Dietary guidelines Advisory Committee published in 2020	Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetselaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Venkatramanan S, Butera G, Terry N, Obbagy J. Dietary Patterns and Bone Health: A Systematic Review. July 2020. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: https://doi.org/10.52570/NESR.DGAC2020.SR0105
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 EH, English LK, Fultz A, Raghavan R, Reigh N, Higgins M, Butera G, Terry N. Dietary Patterns and Bone Health: 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: https://nesr.usda.gov/protocols

* 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^{*} 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 consumed and bone health?

This systematic review updates an existing NESR systematic review that examined dietary patterns consumed and bone health completed by the 2015 and 2020 Dietary Guidelines Advisory Committee[†], which together included evidence published from January 2000 to November 2019. This updated systematic review will synthesize the studies from the existing reviews with eligible studies published since December 2019 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**.

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 in infants, toddlers, 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 bone mass including bone mineral density/content and fracture (in all populations), rickets (in infants, toddlers, children, and adolescents), and osteoporosis and osteopenia (in adults and older adults); the key confounders are sex, age, physical activity, race and/or ethnicity, socioeconomic position, smoking in adults and older adults, alcohol intake in adults and older adults, anthropometry, and estrogen use in adults and 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.

^{*} 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>

[†] Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetelaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Venkatramanan S, Butera G, Terry N, Obbagy J. Dietary Patterns and Bone Health: A Systematic Review. July 2020. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.DGAC2020.SR0105>

Figure 1. Analytic framework for the systematic review question: What is the relationship between dietary patterns consumed and bone health?

<i>Population</i>	<i>Intervention/ exposure</i>	<i>Comparator</i>	<i>Outcome</i>	<i>Key confounders</i>
Infants and toddlers (birth up to 24 months)	Consumption of a dietary pattern	Different dietary pattern(s) Different adherence/ consumption levels to the same dietary pattern	In infants and toddlers, children and adolescents:	<ul style="list-style-type: none"> • Sex • Age • Anthropometry • Socioeconomic position • Race and/or ethnicity • Physical activity
Children and adolescents (2 years up to 19 years)			<ul style="list-style-type: none"> • Bone mass <ul style="list-style-type: none"> • Bone mineral density • Bone mineral content • Fracture • Rickets 	
Adults and older adults (19 years and older)			In adults and older adults: <ul style="list-style-type: none"> • Bone mass <ul style="list-style-type: none"> • Bone mineral density • Bone mineral content • Fracture • Osteoporosis • Osteopenia 	

Synthesis organization:

- I. **Population:** Infants and toddlers, Children and adolescents, Adults, Older adults
 - a. **Outcome:** Bone mass, including bone mineral density; bone mineral content; Rickets (in Infants, toddlers, children, and adolescents); Fracture; Osteoporosis; Osteopenia

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 2**). 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 2. Inclusion and exclusion criteria

Category	Inclusion Criteria	Exclusion Criteria
Study design	<ul style="list-style-type: none"> • Randomized controlled trials • Non-randomized controlled trials[†] • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies 	<ul style="list-style-type: none"> • Uncontrolled trials[†] • Case-control studies • Cross-sectional studies • Ecological studies • Narrative reviews • Systematic reviews • Meta-analyses • Modeling and simulation studies
Publication date	<ul style="list-style-type: none"> • January 2000 – TBD[‡] 	<ul style="list-style-type: none"> • Before January 2000, after TBD
Population: Study participants	<ul style="list-style-type: none"> • Human 	<ul style="list-style-type: none"> • Non-human
Population: Life stage	<ul style="list-style-type: none"> • At intervention or exposure: <ul style="list-style-type: none"> ○ Infants and toddlers (birth up to 24 months) ○ Children and adolescents (2 up to 19 years) ○ Adults and older adults (19 years and older) ○ Individuals during pregnancy ○ Individuals during postpartum • At outcome: <ul style="list-style-type: none"> ○ Infants and toddlers (birth up to 24 months) ○ Children and adolescents (2 up to 19 years) ○ Adults and older adults (19 years and older) ○ Individuals during pregnancy 	<ul style="list-style-type: none"> • At intervention or exposure: <ul style="list-style-type: none"> ○ n/a • At outcome: <ul style="list-style-type: none"> ○ Individuals during pregnancy

^{*} 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 2000 to November 2019

Category	Inclusion Criteria	Exclusion Criteria
Population: Health status	<ul style="list-style-type: none"> • Studies that <u>exclusively</u> enroll participants not diagnosed with a disease* • Studies that enroll <u>some</u> participants: <ul style="list-style-type: none"> ○ diagnosed with a disease; ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ with the outcome of interest; ○ pre- or post-bariatric surgery; ○ and/or hospitalized for an illness, injury, or surgery 	<ul style="list-style-type: none"> • Studies that <u>exclusively</u> enroll participants: <ul style="list-style-type: none"> ○ diagnosed with a disease;† ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ with the outcome of interest (i.e., studies that aim to treat participants who have already been diagnosed with the outcome of interest); ○ receiving pharmacotherapy to treat obesity; ○ pre- or post-bariatric surgery; ○ and/or hospitalized for an illness, injury, or surgery‡
Intervention/ exposure	<ul style="list-style-type: none"> • 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"> ○ 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 • Multi-component intervention in which the isolated effect of the dietary pattern on the outcome(s) of interest is provided or can be determined 	<ul style="list-style-type: none"> • 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) • 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)
Comparator	<ul style="list-style-type: none"> • Consumption of and/or adherence to a different dietary pattern • Different levels of consumption of and/or adherence to a dietary pattern 	<ul style="list-style-type: none"> • Consumption of and/or adherence to a similar dietary pattern of which only a specific component or food source s differs between groups

* 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	Inclusion Criteria	Exclusion Criteria
Outcome(s)	<ul style="list-style-type: none"> • Bone mass <ul style="list-style-type: none"> ○ Bone mineral density ○ Bone mineral content • Fracture • Rickets • Osteoporosis • Osteopenia 	<ul style="list-style-type: none"> • N/A
Confounders	<ul style="list-style-type: none"> • Studies that control for at least one of the key confounders listed in the analytic framework 	<ul style="list-style-type: none"> • Studies that do not control for any of the key confounders listed in the analytic framework
Study duration	<ul style="list-style-type: none"> • Intervention and follow-up length \geq 6 months for < 19-year-olds • Intervention and follow-up length \geq 1 year for > 19-year-olds 	<ul style="list-style-type: none"> • Intervention and follow up length < 6 months for <19-year-olds • Intervention and follow up length < 1 year for > 19-year-olds
Size of study groups	<ul style="list-style-type: none"> • For intervention studies: <ul style="list-style-type: none"> ○ \geq30 participants per study group for between-subject analyses, ○ or a power calculation indicating that the study is appropriately powered for the outcome(s) of interest. 	<ul style="list-style-type: none"> • For intervention studies: <ul style="list-style-type: none"> ○ <30 participants per study group for between-subject analyses, ○ and no power calculation indicating that the study is appropriately powered for the outcome(s) of interest.
Publication status	<ul style="list-style-type: none"> • Peer-reviewed articles published in research journals 	<ul style="list-style-type: none"> • Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings
Language	<ul style="list-style-type: none"> • Published in English 	<ul style="list-style-type: none"> • Not published in English
Country [*]	<ul style="list-style-type: none"> • Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected 	<ul style="list-style-type: none"> • Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected

^{*} 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 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>)

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.*†‡

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 (infants, toddlers, children, adolescents, adults, and older adults). Then, within each of the population groups, the evidence will be organized by similarity in outcome based on the available evidence. Depending on the available evidence, the synthesis may be organized by participant characteristics such as race and/or ethnicity, socioeconomic position, and health status.

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

* 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>

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

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; Emily Levin, MPH, RDN; 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).

Funding: United States Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Alexandria, VA

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 consumed and bone health?

Category	Existing Review	Updated Review	Change and Rationale
Study design	<p><u>Included:</u></p> <ul style="list-style-type: none"> Randomized controlled trials Non-randomized controlled trials (including quasi-experimental and controlled before and after studies) Prospective cohort studies Retrospective cohort studies Nested case-control studies <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Uncontrolled trials Case-control studies Cross-sectional studies Uncontrolled before-and-after studies Narrative reviews Systematic reviews Meta-analyses 	<p><u>Included:</u></p> <ul style="list-style-type: none"> Randomized controlled trials Non-randomized controlled trials[‡] Prospective cohort studies Retrospective cohort studies Nested case-control studies <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Uncontrolled trials[§] Case-control studies Cross-sectional studies Ecological studies Narrative reviews Systematic reviews Meta-analyses Modeling and simulation studies 	Study design criteria were modified to enable focus on the strongest 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>

[†] Boushey C, Ard J, Bazzano L, Heymsfield S, Mayer-Davis E, Sabaté J, Snetelaar L, Van Horn L, Schneeman B, English LK, Bates M, Callahan E, Venkatramanan S, Butera G, Terry N, Obbagy J. Dietary Patterns and Bone Health: A Systematic Review. July 2020. U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. Available at: <https://doi.org/10.52570/NESR.DGAC2020.SR0105>

[‡] Including quasi-experimental and controlled before-and-after studies

[§] 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"> January 2000 – November 2019 <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Before January 2000, after November 2019 	<p><u>Included:</u></p> <ul style="list-style-type: none"> January 2000 – TBD* <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Before January 2000, after TBD 	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"> Human <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Non-human 	<p><u>Included:</u></p> <ul style="list-style-type: none"> Human <p><u>Excluded:</u></p> <ul style="list-style-type: none"> Non-human 	No change
Population: Life stage	<p><u>Included:</u></p> <ul style="list-style-type: none"> At intervention/exposure and outcome: <ul style="list-style-type: none"> Children and adolescents (2 up to 18 years) Adults (19-64 years) Older adults (65 years and older) <p><u>Excluded:</u></p> <ul style="list-style-type: none"> At intervention/exposure and outcome: <ul style="list-style-type: none"> Infants and toddlers (birth up to 24 months) 	<p><u>Included:</u></p> <ul style="list-style-type: none"> At intervention/exposure and outcome: <ul style="list-style-type: none"> Infants and toddlers (birth up to 24 months) Children and adolescents (2 up to 19 years) Adults and older adults (19 years and older) Individuals during postpartum <p><u>Excluded:</u></p> <ul style="list-style-type: none"> At outcome: <ul style="list-style-type: none"> Individuals during pregnancy 	No change other than formatting; In the P/B-24 Project, a separate question addressed dietary patterns during the complementary feeding period and bone health.

* This review update date range encompasses the original systematic review date range, which included articles published from January 2000 to November 2019

Category	Existing Review	Updated Review	Change and Rationale
Population: Health Status	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Studies that enroll participants who are healthy and/or at risk for chronic disease, including those with obesity • Studies that enroll some participants diagnosed with a disease <ul style="list-style-type: none"> ○ Studies that enroll some participants diagnosed with low bone mineral density, low bone mineral content, osteoporosis, osteopenia, rickets, and fracture <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Studies that exclusively enroll participants diagnosed with a disease or hospitalized with an illness or injury. (For this criterion, studies that exclusively enroll subjects with obesity will be included.) • Studies that exclusively enroll participants with osteoporosis, osteopenia, rickets, and fracture (i.e., studies that aim to treat participants who have already been diagnosed with the outcome of interest) 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Studies that exclusively enroll participants not diagnosed with a disease* • Studies that enroll some participants: <ul style="list-style-type: none"> ○ diagnosed with a disease; ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ and/or with the outcome of interest <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Studies that exclusively enroll participants: <ul style="list-style-type: none"> ○ diagnosed with a disease;† ○ hospitalized for an illness, injury, or surgery;‡ ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting; ○ pre- or post-bariatric surgery; ○ and/or receiving pharmacotherapy to treat obesity 	<p>Population health status criteria is modified to exclude those receiving pharmacotherapy to treat obesity.</p>

* 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"> • Studies that examine consumption of and/or adherence to a dietary pattern (such as Dietary Approaches to Stop Hypertension (DASH), vegetarian/vegan, low-carbohydrate, and high-fat diets) • 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 • Studies must describe the dietary pattern being tested or examined, including, at a minimum, the foods and beverages in the pattern <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Studies that do not provide a description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern • This includes studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed, as well as those patterns that are based solely on nutrients 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • 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. • 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. • 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 despite multiple components <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • 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). • Multi-component intervention in which the isolated effect of the intervention of interest on the outcome(s) of interest is not provided or cannot be determined due to multiple components. 	No change other than formatting

Category	Existing Review	Updated Review	Change and Rationale
Comparator	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Consumption of and/or adherence to a different dietary pattern • Different levels of consumption of and/or adherence to a dietary pattern <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • N/A 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Consumption of and/or adherence to a different dietary pattern • Different levels of consumption of and/or adherence to a dietary pattern <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • N/A 	No change
Outcome(s)	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Bone mass including: <ul style="list-style-type: none"> ○ Bone mineral density ○ Bone mineral content • Biomarkers of bone metabolism • Osteoporosis • Osteopenia • Rickets • Fracture <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • N/A 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Bone mass including: <ul style="list-style-type: none"> ○ Bone mineral density ○ Bone mineral content • Osteoporosis • Osteopenia • Rickets • Fracture <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • N/A 	Outcome criteria were modified to enable focus on a stronger body of evidence
Confounders	<p><u>Included</u></p> <ul style="list-style-type: none"> • n/a <p><u>Excluded</u></p> <ul style="list-style-type: none"> • n/a 	<p><u>Included:</u></p> <ul style="list-style-type: none"> • Studies that control for one or more of the key confounders listed in the analytic framework <p><u>Excluded:</u></p> <ul style="list-style-type: none"> • Studies that do not control for any of the key confounders listed in the analytic framework 	Criteria were added to enable focus on a stronger body of evidence.

Category	Existing Review	Updated Review	Change and Rationale
Study duration	<p><u>Included</u></p> <ul style="list-style-type: none"> Minimum length of intervention of 12 weeks <p><u>Excluded</u></p> <ul style="list-style-type: none"> Interventions less than 12 weeks 	<p><u>Included</u></p> <ul style="list-style-type: none"> Intervention and follow-up length \geq 6 months for < 19-year-olds Intervention and follow-up length \geq 1 year for > 19-year-olds <p><u>Excluded</u></p> <ul style="list-style-type: none"> Intervention and follow up length < 6 months for <19-year-olds Intervention and follow up length < 1 year for > 19-year-olds 	<ul style="list-style-type: none"> Study duration criteria were modified to enable focus on a stronger body of evidence
Size of study groups	<p><u>Included</u></p> <ul style="list-style-type: none"> 30 participants per-arm in interventions, or a power calculation included Sample size of 1000 or greater in observational studies <p><u>Excluded</u></p> <ul style="list-style-type: none"> Fewer than 30 participants per arm, or No power calculation reported Fewer than 1000 participants in observational studies 	<p><u>Included:</u></p> <ul style="list-style-type: none"> For intervention studies: <ul style="list-style-type: none"> \geq30 participants per study group for between-subject analyses, or a power calculation indicating that the study is appropriately powered for the outcome(s) of interest <p><u>Excluded:</u></p> <ul style="list-style-type: none"> For intervention studies: <ul style="list-style-type: none"> <30 participants per study group for between-subject analyses, and no power calculation indicating that the study is appropriately powered for the outcome(s) of interest 	<ul style="list-style-type: none"> Size of study groups were modified to include evidence from observational studies with sample sizes less than 1000 participants.
Publication status	<p><u>Included</u></p> <ul style="list-style-type: none"> Articles that have been peer-reviewed <p><u>Excluded</u></p> <ul style="list-style-type: none"> Articles that have not been peer-reviewed and are not published in peer-reviewed journals (e.g., unpublished data, manuscripts, reports, abstracts, pre-prints, and conference proceedings) 	<p><u>Included</u></p> <ul style="list-style-type: none"> Peer-reviewed articles published in research journals <p><u>Excluded</u></p> <ul style="list-style-type: none"> Non-peer reviewed articles, unpublished data or manuscripts, pre-prints, reports, and conference abstracts or proceedings 	<ul style="list-style-type: none"> No change

Category	Existing Review	Updated Review	Change and Rationale
Language	<p><u>Included</u></p> <ul style="list-style-type: none"> Published in English <p><u>Excluded</u></p> <ul style="list-style-type: none"> Not published in English 	<p><u>Included</u></p> <ul style="list-style-type: none"> Published in English <p><u>Excluded</u></p> <ul style="list-style-type: none"> Not published in English 	<ul style="list-style-type: none"> No change
Country*	<p><u>Included</u></p> <ul style="list-style-type: none"> Studies conducted in countries ranked as high or higher human development <p><u>Excluded</u></p> <ul style="list-style-type: none"> Studies conducted in countries ranked as medium or lower human development 	<p><u>Included</u></p> <ul style="list-style-type: none"> Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected <p><u>Excluded</u></p> <ul style="list-style-type: none"> Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected 	<ul style="list-style-type: none"> 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>)