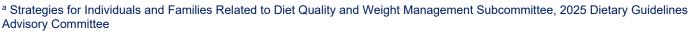
Frequency of Meals and/or Snacking and Energy Intake: A Systematic Review Protocol

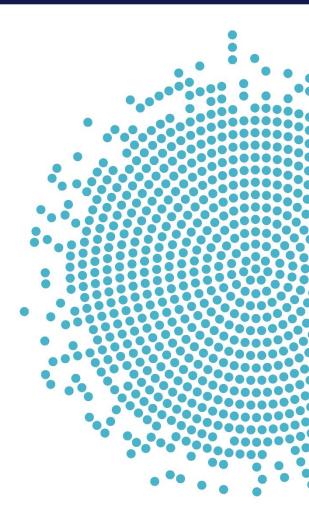
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Suggested citation: Palacios C, Anderson CAM, Andres A, Fisher JO, Gardner CD, Giovannucci E, Hoelscher DM, Jernigan VBB, Odoms-Young A, Raynor HA, Stanford FC, Obbagy J, Callahan EH, Cole NC, Kingshipp BJ, Webster A, Higgins M, Butera G, Terry N. Frequency of Meals and/or Snacking and Energy Intake: 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: <u>https://nesr.usda.gov/protocols</u>

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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 frequency of meals and/or snacking and energy intake?

The Committee will conduct a systematic review to address this question, with support from USDA's Nutrition Evidence Systematic Review (NESR) team (**Table 1**).

Table 1. Review history

Date	Description	Citation
May 2023	Systematic review protocol for the 2025 Dietary Guidelines Advisory Committee published online	Palacios C, Anderson CAM, Andres A, Fisher JO, Gardner CD, Giovannucci E, Hoelscher DM, Jernigan VBB, Odoms-Young A, Raynor HA, Stanford FC, Obbagy J, Callahan EH, Cole NC, Kingshipp BJ, Webster A, Higgins M, Butera G, Terry N. Frequency of Meals and/or Snacking and Energy Intake: 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

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 frequency of meals and/or snacking and energy intake?

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

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

[†] 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: <u>https://nesr.usda.gov/methodology-overview</u>

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.

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 the frequency of meals and/or snacking in toddlers, children, adolescents, adults, and older adults; definitions will vary across studies and include occasion-based measures such as meals (e.g., breakfast), snacking, and number of eating occasions. The comparator is a different frequency of meals and/or snacking. The outcome is energy intake in toddlers, children, adolescents, adults. The key confounders that may impact the relationships of interest are sex, age, physical activity, race and/or ethnicity, socioeconomic position, and anthropometry in all populations, and smoking in adults and older adults.

Figure 1. Analytic framework for the systematic review question: What is the relationship between frequency of meals and/or snacking and energy intake?

Population	Intervention/ exposure	Comparator	Outcome	Key confounders
Toddlers, children, and adolescents (1 up to 19 years) Adults and older adults (19 years and older)	Frequency of meals and/or snacking*	Different frequency of meals and/or snacking	In toddlers, children, adolescents, adults, and older adults: • Energy intake	 Sex Age Physical activity Race and/or ethnicity Socioeconomic position Anthropometry Smoking (adults, older adults)

* Definitions will vary across studies and include occasion-based measures such as meals (e.g., breakfast), snacking, and number of eating occasions.

Synthesis organization:

- I. Intervention/Exposure: Meals (e.g., breakfast); Snacking; Number of eating occasions
 - a. *Population:* Toddlers; Children; Adolescents; Adults; Older adults
 - i. Outcome: Energy intake

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	 Randomized controlled trials Non-randomized controlled trials* Prospective cohort studies Retrospective cohort studies Nested case-control studies 	 Uncontrolled trials[†] Case-control studies Cross-sectional studies Ecological studies Narrative reviews Systematic reviews Meta-analyses Modeling and simulation studies
Publication date	• January 2000 – May 2023	Before January 2000, after May 2023
Population: Study participants	• Human	• Non-human
Population: Life stage	 At intervention or exposure and outcome: Toddlers (12 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 intervention or exposure and outcome: Infants (birth up to 12 months)

^{*} Including quasi-experimental and controlled before-and-after studies

[†] Including uncontrolled before-and-after studies

Category	Inclusion Criteria	Exclusion Criteria		
Population: Health status	 Studies that <u>exclusively</u> enroll participants not diagnosed with a disease[*] Studies that enroll <u>some</u> participants: diagnosed with a disease; diagnosed with a disorder that affects feeding/eating or growth (e.g., autism spectrum disorder, attention-deficit/hyperactivity disorder, eating disorders); with severe undernutrition, failure to thrive/underweight, stunting, or wasting; receiving pharmacotherapy to treat obesity; pre- or post-bariatric surgery; and/or hospitalized for an illness, injury, or surgery 	 Studies that <u>exclusively</u> enroll participants: diagnosed with a disease;[†] diagnosed with a disorder that affects feeding/eating or growth (e.g., autism spectrum disorder, attention-deficit/hyperactivity disorder, eating disorders); with severe undernutrition, failure to thrive/underweight, stunting, or wasting; receiving pharmacotherapy to treat obesity; pre- or post-bariatric surgery; and/or hospitalized for an illness, injury, or surgery[‡] 		
Intervention/ Exposure	 Frequency of meals and/or snacking. Definitions will vary across studies and include occasion-based measures such as: Meals (e.g., breakfast) Snacking Number of eating occasions 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 	 Studies that only examine frequency of intake of a single food, beverage or category of foods and/or beverages (e.g., frequency of cereal consumption, frequency of dairy consumption, frequency of snack foods) 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 		
Comparator	Different frequency of meals and/or snacking	• N/A		
Outcome(s)	Energy intake	• N/A		
Publication status	Peer-reviewed articles published in research journals	 Non-peer-reviewed articles, unpublished data or manuscripts, pre-prints, reports, editorials, retracted articles, and conference abstracts or proceedings 		
Language	Published in English	Not published in English		
Country [§]	• Studies conducted in countries classified as high or very high on the Human Development Index the year(s) the intervention/exposure data were collected	• Studies conducted in countries classified as medium or low on the Human Development Index the year(s) the intervention/exposure data were collected		

^{*} 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

[§] The classification of countries on the Human Development Index (HDI) is based on the UN Development Program Human Development Report Office (<u>http://hdr.undp.org/en/data</u>) 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 intervention/exposure. Then, within each intervention/exposure, the evidence will be organized by population. 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 and/or ethnicity, socioeconomic position, and health status.

Develop conclusion statements 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. <u>https://www.riskofbias.info/welcome/robins-e-tool</u>

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 (Meghan Adler, MS, RDN; Carolyn Chung, PhD; Dana DeSilva, PhD, RD; Chinwe Obudulu, MS, RD, LD; Elizabeth Rahavi, RD) and Project Leadership (HHS: Janet de Jesus, MS, RD; USDA: Eve Stoody, PhD), supports the Committee by facilitating, executing, and documenting the work necessary to ensure the reviews are completed in accordance with NESR methodology.

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