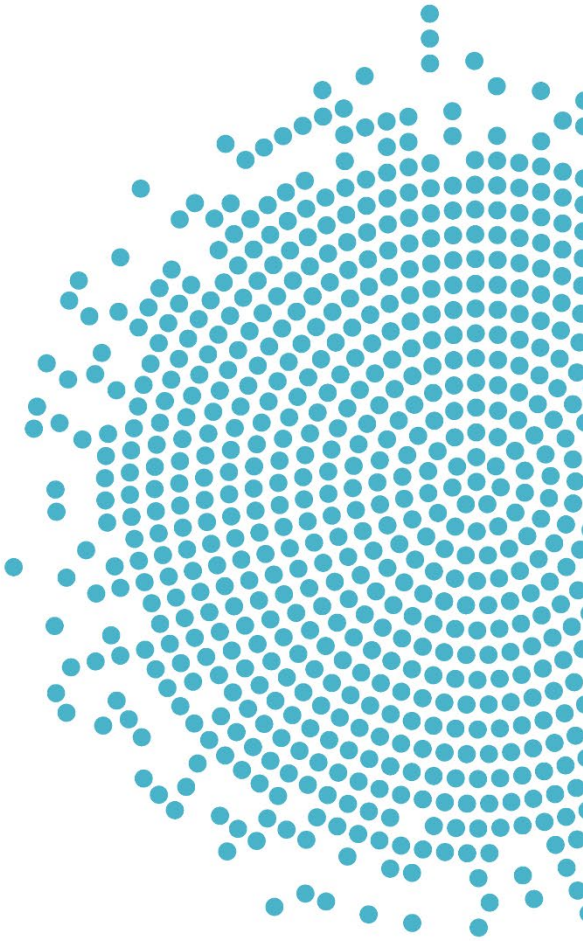
USDA
UNITED STATES DEPARTMENT OF AGRICULTURE

Coffee and Tea and Risk of Type 2 Diabetes: A Systematic Review Protocol



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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 coffee and/or tea consumption and risk of type 2 diabetes?

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	Hoelscher DM, Anderson CAM, Booth SL, Deierlein AL, Fung TT, Gardner CD, Giovannucci E, Raynor HA, Stanford FC, Talegawkar SA, Taylor CA, Tobias DK, Obbagy J, Cole NC, Kingshipp B, Webster A, Higgins M, Butera G, Terry N. Coffee and Tea and Risk of Type 2 Diabetes: 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
February 2024	Systematic review discontinued by the 2025 Dietary Guidelines Advisory Committee	N/A **Rationale for discontinuation**: In consideration of project workload and timelines, the Committee discontinued this systematic review after determining that assessing the overall dietary pattern in relation to risk of type of 2 diabetes is higher priority than examining coffee and tea independently. In addition, the nutritional implications of consuming this beverage type are being examined in other systematic reviews and food pattern modeling analyses.

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 coffee and/or tea consumption and risk of type 2 diabetes?

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

[†] 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

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.

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 coffee and/or tea consumption in infants, toddlers, children, adolescents, adults, and older adults. The comparators are consumption of a different amount of coffee and/or tea (including no consumption and versions diluted with water), coffee and/or tea with varying levels of fat or sweetener, or water. The outcomes include fasting blood glucose, fasting insulin, glucose tolerance/insulin resistance, hemoglobin A1c, prediabetes, and risk of type 2 diabetes in infants, toddlers, children, adolescents, adults, and older adults. The key confounders that may impact the relationships of interest are sex, age, race and/or ethnicity, socioeconomic position, anthropometry, physical activity, and family history of diabetes in all populations, and smoking and alcohol intake in adults and older adults.

Figure 1. Analytic framework for the systematic review question: What is the relationship between coffee and/or tea consumption and risk of type 2 diabetes?

Population	***Intervention/ exposure***	***Comparator***	***Outcome***	***Key confounders***
Infants and toddlers (birth up to 24 months) Children and adolescents (2 up to 19 years) Adults and older adults (19 years and older)	Coffee and/or tea consumption	Consumption of a different amount of coffee and/or tea (including no consumption and versions diluted with water) Coffee and/or tea with varying levels of fat or sweetener Coffee and/or tea vs. water	In infants, toddlers, children, adolescents, adults, and older adults: • Fasting blood glucose • Fasting insulin • Glucose tolerance/insulin resistance • Hemoglobin A1C • Prediabetes • Type 2 diabetes	• Sex • Age • Race and/or ethnicity • Socioeconomic position • Anthropometry • Physical activity • Family history of diabetes • Smoking (adults, older adults) • Alcohol intake (adults, older adults)

Synthesis organization:

I. ***Intervention/exposure:*** Coffee; Tea; Coffee + Tea

   a. ***Population:*** Infants and toddlers; Children and adolescents; Adults; Older adults

      i. ***Outcome:*** Fasting blood glucose; Fasting insulin; Glucose tolerance/insulin resistance; Hemoglobin A1C; Prediabetes; Type 2 diabetes

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 • Mendelian randomization 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 – TBD	• Before January 2000, after TBD
Population: Study participants	• Human	• Non-human

Population: Life stage	• At intervention or exposure and outcome:
	  ○ Infants and toddlers (birth up to 24 months)
	  ○ Children and adolescents (2 up to 19 years)
	  ○ Adults and older adults (19 years and older)
	• At intervention or exposure:
	  ○ Individuals during pregnancy
		• At intervention or exposure:
		  ○ N/A
		• At outcome:
		  ○ Individuals during pregnancy

[*] 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 exclusively enroll participants not diagnosed with a disease[*]
	• Studies that enroll some participants:
	  ○ diagnosed with a disease;
	  ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;
	  ○ born preterm,[†] with low birth weight,[‡] and/or small for gestational age;
	  ○ with the outcome of interest;
	  ○ receiving pharmacotherapy to treat obesity;
	  ○ pre- or post-bariatric surgery;
	  ○ and/or hospitalized for an illness, injury, or surgery
		• Studies that exclusively enroll participants:
		  ○ diagnosed with a disease;[§]
		  ○ with severe undernutrition, failure to thrive/underweight, stunting, or wasting;
		  ○ born preterm,[†] with low birth weight,[‡] and/or small for gestational age;
		  ○ 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	• Coffee and/or tea consumption • 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	• Infant milk, infant formula, toddler formula/milks • Other beverage types, such as nutritional beverages (e.g., protein shakes, smoothies) • Studies focusing on specific nutrients added to beverages instead of a beverage as a whole (i.e., studies where beverages are the delivery mechanism for a nutrient) • Beverages that are not commercially available (e.g., experimentally manipulated beverages) • Supplements • Alcohol • Soups • 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	• Consumption of a different amount of coffee and/or tea (including no consumption and versions diluted with water) • Coffee and/or tea with varying levels of fat or sweetener • Coffee and/or tea vs. water	• No comparator

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

[†] Gestational age <37 weeks and 0/7 days

[‡] Birth weight <2500g

[§] 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)	• Fasting blood glucose • Fasting insulin • Glucose tolerance/insulin resistance • Hemoglobin A1C • Prediabetes • Type 2 diabetes	• Urinary measures of glucose • Non-fasting blood glucose • Non-fasting insulin • Gestational diabetes
Study duration*	• Intervention length ≥12 weeks for hemoglobin A1C, prediabetes, and type 2 diabetes; ≥4 weeks for fasting blood glucose, fasting insulin, and glucose tolerance/insulin resistance	• Intervention length <12 weeks for hemoglobin A1C, prediabetes, and type 2 diabetes; <4 weeks for fasting blood glucose, fasting insulin, and glucose tolerance/insulin resistance
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

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

* Study duration criteria were developed to enable focus on a stronger body of evidence.

† 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)

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 similar 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.

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;

[*] 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:l4898.doi:10.1136/bmj.l4898

[†] 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

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 Stoody, 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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