WHAT IS THE RELATIONSHIP BETWEEN DIETARY PATTERNS CONSUMED AND GROWTH, SIZE, BODY COMPOSITION, AND RISK OF OVERWEIGHT AND OBESITY?: SYSTEMATIC REVIEW PROTOCOL

This document describes the protocol for a systematic review to answer the following question: What is the relationship between dietary patterns consumed and growth, size, body composition, and risk of overweight and obesity?

The 2020 Dietary Guidelines Advisory Committee, Dietary Patterns subcommittee, will be answering this question by conducting a systematic review with support from USDA's Nutrition Evidence Systematic Review (NESR), part of which involves updating an existing systematic review.

NESR methodology for answering a systematic review question involves:

- searching for and selecting articles,
- extracting data and assessing the risk of bias of results from each included article,
- synthesizing the evidence,
- developing a conclusion statement,
- grading the evidence underlying the conclusion statement, and
- recommending future research.

More information about NESR's systematic review methodology, which will be used in this systematic review update, is available on the NESR website: https://nesr.usda.gov/2020-dietary-guidelines-advisory-committee-systematic-reviews.

The existing NESR systematic review that will be updated as part of this work was conducted for the 2014 Dietary Patterns Systematic Review Project by a Technical Expert Collaborative and staff from USDA's NESR. Complete documentation of the systematic review is available on NESR's website:

https://nesr.usda.gov/sites/default/files/2019-04/DietaryPatternsReport-FullFinal.pdf

In addition, more information about NESR's systematic review methodology for the existing review is available on the NESR website:

 Methodology from the 2014 Dietary Patterns Systematic Review Project: https://nesr.usda.gov/dietary-patterns-systematic-review-project-methodology

This document includes details about the methodology used for updating the systematic reviews described above and will be applied to the updated systematic review as follows:

- The <u>analytic framework</u> (p. 3) illustrates the overall scope of the question, including the population, the interventions and/or exposures, comparators, and outcomes of interest.
- The <u>literature search and screening plan</u> (p. 4) details the electronic databases and <u>inclusion and exclusion criteria</u> (p. 4) that will be used to search for, screen, and select articles to be included in the systematic review.
- The <u>literature search and screening results</u> (p. 8) includes a list of included articles, and a list of excluded articles with the rationale for exclusion.

This protocol is up-to-date as of: 09/19/2019.

This version of the protocol contains updates to the following sections. These changes do not reflect a substantive change in the intent or conduct of the review.

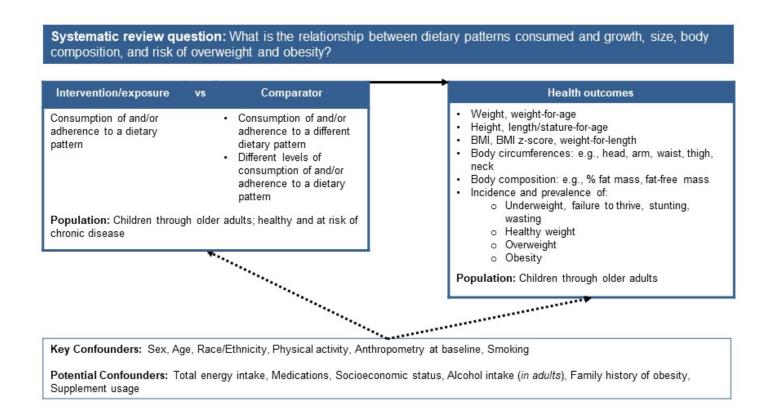
Other factors to be considered were added to the analytic framework for transparency.

- The key confounder of "total energy intake" was moved to "other factors to be considered" on the analytic framework.
- The inclusion and exclusion criteria for the date of publication was updated from July to September to reflect when the literature search will be completed.
- The inclusion and exclusion criteria for the intervention/exposure were edited to clarify that only studies that describe all macronutrients (i.e., carbohydrate, fat, and protein) in the diet will be included.
- The inclusion and exclusion criteria for the date of publication were edited to include literature that examines macronutrient proportion diets in articles published prior to 2014 that were not included in the existing review.

ANALYTIC FRAMEWORK

The analytic framework (**Figure 1**) illustrates the overall scope of the systematic review, including the population, the interventions and/or exposures, comparators, and outcomes of interest. It also includes definitions of key terms and identifies key confounders and other factors to be considered in the systematic review. The inclusion and exclusion criteria that follow provide additional information about how parts of the analytic framework will be defined and operationalized for the review.

Figure 1: Analytic framework



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.

Legend

The relationship of interest in the systematic review
Factors that may impact the relationship of interest in the systematic review

LITERATURE SEARCH AND SCREENING PLAN

Electronic databases

Listed below are the databases that will be searched to identify all potentially relevant articles that have been published to address the systematic review question. Additional details regarding the search strategy will be published upon completion of the review, and are available upon request prior to publication.

- PubMed
- Cochrane
- Embase

Inclusion and exclusion criteria

This table provides the inclusion and exclusion criteria for the systematic review. The inclusion and exclusion criteria are a set of characteristics that will be used to determine which articles identified in the literature search will be included or excluded in the systematic review.

Table 1. Inclusion and exclusion criteria

Category	Inclusion Criteria	Exclusion Criteria
Study design	 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 	 Uncontrolled trials Case-control studies Cross-sectional studies Uncontrolled before-and-after studies Narrative reviews Systematic reviews Meta-analyses

Category	Inclusion Criteria	Exclusion Criteria
Intervention/ exposure ⁱ	 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 	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
	 Studies that examine consumption of and/or adherence to a specific macronutrient proportion diet (i.e., studies that examine a diet where the level of the macronutrient is outside of the AMDR such as low- carbohydrate diet <45% of energy from carbohydrate or a high-fat diet of >35% of energy from fat) 	 Studies that do not provide a description of or examine a specific % of energy from macronutrients (i.e., low-carbohydrate diet <45% of energy from carbohydrate or a high-fat diet >35% of energy from fat) Studies that do not describe all of the macronutrients in the diet (i.e., carbohydrate, fat, and protein)
Comparator	 Consumption of and/or adherence to a different dietary pattern Different levels of consumption of and/or adherence to a dietary pattern 	N/A
	Studies that examine adherence to and/or or consumption of a different macronutrient proportion diet	

¹ The existing NESR systematic reviews included studies that examined low-carbohydrate and/or high-fat diets for the intervention/exposure and comparator. In this update to the existing review, studies that examine low-carbohydrate and/or high-fat diets will still be included and must follow the Acceptable Macronutrient Distribution Ranges (AMDR) for percentage of energy from those macronutrients (i.e., low-carbohydrate diet <45% of energy from carbohydrate or a high-fat diet of >35% of energy from fat). The rationale is to be comprehensive to high priority diets of public health interest.

Category	Inclusion Criteria	Exclusion Criteria	
Outcomesii	 Weight, weight-for-age Height, length/stature-for-age BMI, BMI z-score, weight-for-length Body circumferences e.g., head, arm, waist, thigh, neck Body composition and distribution (e.g., % fat mass, fat-free mass) Incidence and prevalence of: Underweight, failure to thrive, stunting, wasting Healthy weight Overweight Obesity 	Gestational weight gain	
Date of publication	August 2013 – September 2019 (this date range is in addition to the original systematic review, which included articles published from January 1980-July 2013)	Articles published prior to January 1980 or after September 2019	
	 Additional search to cover macronutrient proportion diets: January 2000 – August 2013 	 Additional search to cover macronutrient proportion diets: Articles published prior to 2000 	
Publication status	Articles that have been peer-reviewed	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)	
Language of publication	Articles published in English	Articles published in languages other than English	
Country ⁱⁱⁱ	Studies conducted in countries ranked as high or higher human development	Studies conducted in countries ranked as medium or lower human development	

ⁱⁱ The Pregnancy and Lactation Subcommittee of the 2020 Dietary Guidelines Advisory Committee will address dietary patterns during pregnancy and lactation in relation to gestational weight gain and postpartum weight loss (respectively).

iii The Human Development classification was based on the Human Development Index (HDI) ranking from the year the

Category	Inclusion Criteria	Exclusion Criteria
Study participants	 Human participants Males Females Women during pregnancy and lactation 	Non-human participants (i.e., animals)
Age of study participants	 Age at intervention or exposure: Children and adolescents (ages 2-18 years) Adults (ages 19-64 years) Older adults (ages 65 years and older) 	 Age at intervention or exposure: N/A Infants and toddlers (birth to 24 months)
	 Age at outcome: Children and adolescents (ages 2-18 years) Adults (ages 19-64 years) Older adults (ages 65 years and older) 	 Age at outcome Infants and toddlers (birth to 24 months)
Health status of study participants	 Studies that enroll participants who are healthy and/or at risk for chronic disease Studies that enroll some participants diagnosed with a disease Studies that enroll some participants who are classified with severe undernutrition, or as underweight, stunted, or obese 	 Studies that exclusively enroll participants diagnosed with a disease, or hospitalized with an illness or injury Studies that exclusively enroll participants classified as obese (i.e., studies that aim to treat participants who have already been classified as obese) or who are post-bariatric surgery

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).

LITERATURE SEARCH AND SCREENING RESULTS

This protocol will be updated with the literature search and screening results after the search and screening plan has been finalized and implemented.

The flow charts (**Figure 2 and 3**) below illustrate the literature search and screening results for articles examining the update to this systematic review question. The results of the electronic database searches, after removal of duplicates, were screened independently by two NESR analysts using a step-wise process by reviewing titles, abstracts, and full-texts to determine which articles met the inclusion criteria. A manual search was done to find articles that were not identified when searching the electronic databases; all manually identified articles are also screened to determine whether they meet criteria for inclusion.

Figure 2: Flow chart of literature search and screening results from the existing review (To be added)

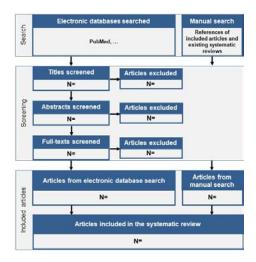
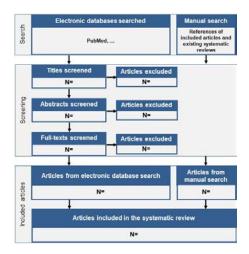


Figure 3: Flow chart of literature search and screening results from the updated review (To be added)



Included Articles from Existing Literature Search (To be added)

1. Ref

Included Articles from Updated Literature Search (To be added)

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Excluded Articles from Updated Literature Search (To be added)

The table below lists the articles excluded after full-text screening for the update to this systematic review question. At least one reason for exclusion is provided for each article, which may not reflect all possible reasons. Information about articles excluded after title and abstract screening is available upon request.

Table 2. Excluded articles

Citation	Rationale
1	