Quality Criteria Checklist: Primary Research

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS					
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes	No	Unclear	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes	No	Unclear	N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes	No	Unclear	N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes	No	Unclear	N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
1.	**Was the <u>research question</u> clearly stated?**	Yes	No	Unclear	N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?				
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?				
1.3	Were the target population and setting specified?				
2.	**Was the <u>selection</u> of study subjects/patients free from bias?**	Yes	No	Unclear	N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?				
2.2	Were criteria applied equally to all study groups?				
2.3	Were health, demographics, and other characteristics of subjects described?				
2.4	Were the subjects/patients a representative sample of the relevant population?				
3.	**Were <u>study groups comparable</u>?**	Yes	No	Unclear	N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)				
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?				
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)				
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?				
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)				
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?				
4.	**Was method of handling <u>withdrawals</u> described?**	Yes	No	Unclear	N/A
4.1	Were follow up methods described and the same for all groups?				
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)				
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?				
4.4	Were reasons for withdrawals similar across groups?				
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?				
5.	**Was <u>blinding</u> used to prevent introduction of bias?**	Yes	No	Unclear	N/A
5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?				

	5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) 5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? 5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status? 5.5 In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?** 6.1 In RCT or other intervention trial, were protocols described for all regimens studied? 6.2 n observational study, were interventions, study settings, and clinicians/provider described? 6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? 6.4 Was the amount of exposure and, if relevant, subject/patient compliance measured? 6.5 Were co-interventions (e.g., ancillary treatments, other therapies) described? 6.6 Were extra or unplanned treatments described? 6.7 Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? 6.8 In diagnostic study, were details of test administration and replication sufficient?	Yes No Unclear N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?** 7.1 Were primary and secondary endpoints described and relevant to the question? 7.2 Were nutrition measures appropriate to question and outcomes of concern? 7.3 Was the period of follow-up long enough for important outcome(s) to occur? 7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? 7.5 Was the measurement of effect at an appropriate level of precision? 7.6 Were other factors accounted for (measured) that could affect outcomes? 7.7 Were the measurements conducted consistently across groups?	Yes No Unclear N/A
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?** 8.1 Were statistical analyses adequately described the results reported appropriately? 8.2 Were correct statistical tests used and assumptions of test not violated? 8.3 Were statistics reported with levels of significance and/or confidence intervals? 8.4 Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? 8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? 8.6 Was clinical significance as well as statistical significance reported? 8.7 If negative findings, was a power calculation reported to address type 2 error?	Yes No Unclear N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?** 9.1 Is there a discussion of findings? 9.2 Are biases and study limitations identified and discussed?	Yes No Unclear N/A
10.	**Is bias due to study's funding or sponsorship unlikely?** 10.1 Were sources of funding and investigators' affiliations described? 10.2 Was there no apparent conflict of interest?	Yes No Unclear N/A
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.*		
NEUTRAL (∅) *If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.*		
PLUS/POSITIVE (+) *If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Worksheet.*		

Quality Criteria Checklist: Primary Research: Non-human Subjects

Symbols Used

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-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research: Non-human Subjects

RELEVANCE QUESTIONS	
1. Would implementing the studied intervention, procedure or product (if found successful) result in improved outcomes for the patients/clients/target population group? (NA for some Epi studies)	Yes No Unclear N/A
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/target population group would care about?	Yes No Unclear N/A
3. Is the focus of the intervention, procedure or product (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No Unclear N/A
4. Is the intervention, procedure or product feasible for application in dietetic practice?	Yes No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.	
VALIDITY QUESTIONS	
1. Was the <u>research question</u> clearly stated? 1.1 Was the specific intervention(s) or procedure (independent variable(s))or exposure factor, process or product of interest identified? 1.2 Was the outcome(s) (dependent variable(s)) or status or condition of interest clearly indicated? 1.3 Were the study context and setting specified?	Yes No Unclear N/A
2. Was the <u>selection</u> of study subjects/units to be free from bias? 2.1 Were eligibility criteria (inclusion/exclusion) specified with sufficient detail and without omitting criteria critical to the study? 2.2 Were criteria applied equally to all units of observation and all study groups? 2.3 Was the source and other relevant characteristics of units of observation described? 2.4 Were the selected units a representative sample of the context and setting for application of study findings?	Yes No Unclear N/A
3. Were <u>study groups comparable</u> or was an appropriate reference standard used? 3.1 Was the method of assigning subjects/units of observation described and unbiased? (Method of randomization identified if RCT) 3.2 Was the distribution of relevant characteristics similar across subjects/units of observation and study groups at baseline? 3.3 Were concurrent controls used? (Concurrent comparison data preferred over historical data.) 3.4 If a cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? 3.5 If diagnostic, validity or reliability study, was there a comparison with an appropriate reference standard? **NOTE:** Criterion #3 is NA if only one group was studied, comparison groups were not constructed for analysis, and a comparison to a reference standard not made.	Yes No Unclear N/A
4. Were methods of handling losses from the original sample (withdrawals) described? 4.1 Were follow-up methods described and the same for all subjects/units of observation and groups? 4.2 Were the number, characteristics of withdrawn units (i.e., damaged specimen, dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for the sample and each group? 4.3 Were all enrolled subjects/units (in the original sample) accounted for?	Yes No Unclear N/A

	4.4	Were reasons for withdrawal or loss similar across groups?	
	4.5	If diagnostic test, was decision to perform reference test not dependent on results of the diagnostic method under study?	
5.	**Was <u>blinding</u> used to prevent introduction of bias?**		Yes No Unclear N/A
	5.1	Were field and research staff and investigators blinded to treatment group, as appropriate?	
	5.2	Were data collectors blinded for outcomes assessment? (If the outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In a cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic, reliability or validity study, were test results blinded to unit of observation history and other test results??	
6.	**Was the intervention/treatment regimen/exposure factor, procedure, process or product of interest and any comparison(s) described in detail? Were <u>intervening factors</u> described?**		Yes No Unclear N/A
	6.1	Were protocols described for all alternatives studied?	
	6.2	Was the context (study setting, intervention or exposure details or process, involved personnel, etc) described?	
	6.3	Was the intensity and duration of the treatment or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was fidelity to the research plan documented and the actual amount of exposure, if relevant, measured, and are data free from bias?	
	6.5	Were co-interventions (e.g., concurrent ancillary treatments or procedures, other therapies) described?	
	6.6	Were extra or unplanned interventions or environmental influences during the study period described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all units of observation and all groups?	
	6.8	In diagnostic , validity or reliability study, were details of test administration and replication sufficiently described?	
7.	**Were <u>outcomes</u> or condition or status of interest clearly defined and the <u>measurements valid and reliable</u>?**		Yes No Unclear N/A
	7.1	Were key outcomes (including primary and secondary endpoints, if applicable) described and relevant to the question?	
	7.2	Were nutrition-related outcomes measures, if included, appropriate to the study question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of outcomes or effect at an appropriate level of precision?	
	7.6	Were other factors that could affect outcomes (e.g., confounders) measured or accounted for?	
	7.7	Were the measurements conducted consistently across units of observation, groups and time periods?	
8.	**Was the <u>statistical analysis</u> appropriate for the study design and type of outcome indicators?**		Yes No Unclear N/A
	8.1	Were statistical analyses adequately described and the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was there a clear description of subjects/units observed included in each analysis? If appropriate, was there a dose-response analysis?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical or pragmatic significance as well as statistical significance reported?	
	8.7	Was a power calculation reported to address adequate sample size to measure effect and avoid type 2 error? (This is especially important if findings are negative.)	
9.	**Are <u>conclusions supported by results</u> with biases and limitations taken into consideration?**		Yes No Unclear N/A
	9.1	Is there an adequate discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study's <u>funding or sponsorship</u> unlikely?**		Yes No Unclear N/A

10.1 Were sources of funding and investigators' affiliations described? 10.2 Was there no apparent conflict of interest?	
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.*	
NEUTRAL (∅) *If the answers to validity criteria questions 2, 3, 6, and 7 are "Yes" but several other criteria indicate study weaknesses, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.*	
PLUS/POSITIVE (+) *If most (six or more) of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7), the report should be designated with a plus symbol (+) on the Evidence Worksheet.*	
When a validity criteria question is NA *If any of the ten validity questions are NA, the report requires a majority of "Yes" answers (including 2, 3, 6, 7, as applicable) for a plus (+), or a majority or "No" answers for a minus (-) rating.*	

Quality Criteria Checklist: Review Article

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-- **Negative:** Indicates that these issues have not been adequately addressed.

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Quality Criteria Checklist: Review Articles

RELEVANCE QUESTIONS					
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes	No	Unclear	N/A
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes	No	Unclear	N/A
3.	Is the problem addressed in the review one that is relevant to dietetics practice?	Yes	No	Unclear	N/A
4.	Will the information, if true, require a change in practice?	Yes	No	Unclear	N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
1.	Was the question for the review clearly focused and appropriate?	Yes	No	Unclear	N/A
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?	Yes	No	Unclear	N/A
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes	No	Unclear	N/A
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes	No	Unclear	N/A
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes	No	Unclear	N/A
6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes	No	Unclear	N/A
7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes	No	Unclear	N/A
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes	No	Unclear	N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes	No	Unclear	N/A
10.	Was bias due to the review's funding or sponsorship unlikely?	Yes	No	Unclear	N/A
MINUS/NEGATIVE (-) *If most (six or more) of the answers to the above validity questions are "No," the review should be designated with a minus (-) symbol on the Evidence Quality Worksheet.*					
NEUTRAL (∅) *If the answer to any of the first four validity questions (1-4) is "No," but other criteria indicate strengths, the review should be designated with a neutral (∅) symbol on the Evidence Worksheet.*					
PLUS/POSITIVE (+) *If most of the answers to the above validity questions are "Yes" (must include criteria 1, 2, 3, and 4), the report should be designated with a plus symbol (+) on the Evidence Worksheet.*					