****Academy of Nutrition and Dietetics  
Evidence Analysis Library® Worksheet Template and  
Quality Criteria Checklist: Primary Research Non-human Subjects**

|  |  |
| --- | --- |
| Citation |  |
| Study Design |  |
| Class |  |
| Quality Rating | + (Positive)  - (Negative)  ⦸ (Neutral) |
| Research Purpose |  |
| Inclusion Criteria |  |
| Exclusion Criteria |  |
| Description of Study Protocol | Recruitment:  Design:  Blinding used (if applicable):  Intervention (if applicable):  Statistical Analysis: |
| Data Collection Summary | Timing of Measurements:  Dependent Variables:  Independent Variables:  Control Variables: |
| Description of Actual Data Sample | Initial:       (      Males       Females)  Attrition (final N):  Age:  Ethnicity:  Other relevant demographics:  Anthropometrics:  Location: |
| Summary of Results | Key Findings:  Other Findings: |
| Author Conclusion |  |
| Reviewer Comments |  |
| Funding Source |  |

**Quality Criteria Checklist: Primary Research Non-human Studies**

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| --- | --- |
| Symbols Used | Explanation |
| + | **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 week |

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| --- | --- | --- |
| **Relevance Questions** | | |
| 1. Would implementing the studied intervention, procedure or product (if found successful) result in improved outcomes for the patients/clients/population group? | **1** | Select a Rating |
| 1. Did the authors study an outcome (dependent variable) or topic that the patients/clients/target population group would care about? | **2** | Select a Rating |
| 1. Is the focus of the intervention, procedure or product (independent variable) or topic of study a common issue of concern to dietetics practice? | **3** | Select a Rating |
| 1. Is the intervention, procedure or product feasible for application in dietetics practice? | **4** | Select a Rating |
| ***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 research question clearly stated?**    1. Was the specific intervention(s) or procedure (independent variable(s)) or exposure factor, process or product of interest identified?    2. Was the outcome(s) (dependent variable(s)) or status or condition of interest clearly indicated?    3. Were the study context and setting specified? | 1 | Select a Rating |
| 1.1 | Select a Rating |
| 1.2 | Select a Rating |
| 1.3 | Select a Rating |
| 1. **Was the selection of study subjects/units free from bias?**    1. Were eligibility criteria (inclusion/exclusion) specified with sufficient detail and without omitting criteria critical to the study?    2. Were criteria applied equally to all units of observation and all study groups?    3. Was the source and other relevant characteristics of units of observation described?    4. Were the selected units a representative sample of the context and setting for application of study findings? | 2 | Select a Rating |
| 2.1 | Select a Rating |
| 2.2 | Select a Rating |
| 2.3 | Select a Rating |
| 2.4 | Select a Rating |
| 1. **Were study groups comparable or was an appropriate reference standard used?**    1. Was the method of assigning subjects/units of observation to groups or assigning treatments to units of observation described and unbiased? (Method of randomization indentified if RCT)    2. Was the distribution of relevant characteristics similar across subjects/units of observation and study groups at baseline?    3. Were concurrent controls used? (Concurrent comparison data preferred over historical data.)    4. If a cross-sectional study, were groups comparable on important confounding factors and/or were pre-existing differences accounted for by using appropriate adjustments in statistical analysis? (Sub-question not used (NA)    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. | 3 | Select a Rating |
| 3.1 | Select a Rating |
| 3.2 | Select a Rating |
| 3.3 | Select a Rating |
| 3.4 | Select a Rating |
| 3.5 | Select a Rating |

|  |  |  |
| --- | --- | --- |
| 1. **Were methods of handling losses from the original sample (withdrawals) described?**    1. Were follow-up methods described and the same for all subjects/units of observation and groups?    2. Were the number, characteristics of withdrawal 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?    3. Were all enrolled subjects/units (in the original sample) accounted for?    4. Were reasons for withdrawal or loss similar across groups?    5. If diagnostic test, was decision to perform reference test not dependent on results of the diagnostic method under study? | 4. | Select a Rating |
| 4.1 | Select a Rating |
| 4.2 | Select a Rating |
| 4.3 | Select a Rating |
| 4.4 | Select a Rating |
| 4.5 | Select a Rating |
| 1. **Was blinding used to prevent introduction of bias?**    1. Were field and research staff and investigators blinded to treatment group, as appropriate?    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).    3. In a cross-sectional study, were measurements of outcomes and risk factors blinded?    4. In case control study, was case definition explicit and case ascertainment not influenced by exposure status?    5. In diagnostic, reliability or validity study, were test results blinded to unit of observation history and other test results? | 5 | Select a Rating |
| 5.1 | Select a Rating |
| 5.2 | Select a Rating |
| 5.3 | Select a Rating |
| 5.4 | Select a Rating |
| 5.5 | Select a Rating |
| 1. **Was the intervention/treatment regimens/exposure factor, procedure, process or product of interest and any comparison(s) described in detail? Were intervening factors described?**    1. Were protocols described for all alternatives studies?    2. Was the context (study setting, intervention or exposure details or process, involved personnel, etc.) described?    3. Was the intensity and duration of the treatment or exposure factor sufficient to produce a meaningful effect?    4. Was fidelity to the research plan documented and the actual amount of exposure, if relevant, measured and are data free from bias?    5. Were co-interventions (e.g., concurrent ancillary treatments or procedures, other therapies) described?    6. Were extra or unplanned interventions or environmental influences during the study period described?    7. Was the information for 6.4, 6.5, and 6.6 assessed the same way for all units of observation and all groups?    8. In diagnostic, validity or reliability study, were details of test administration and replication sufficiently described? | 6 | Select a Rating |
| 6.1 | Select a Rating |
| 6.2 | Select a Rating |
| 6.3 | Select a Rating |
| 6.4 | Select a Rating |
| 6.5 | Select a Rating |
| 6.6 | Select a Rating |
| 6.7 | Select a Rating |
| 6.8 | Select a Rating |
| 1. **Were outcomes or condition or status of interest clearly defined and the measurements valid and reliable?**    1. Were key outcomes (including primary and secondary endpoints, if applicable) described and relevant to the question?    2. Were nutrition-related outcomes measures, if included, appropriate to the study question and outcomes of concern?    3. Was the period of follow-up long enough for important outcome(s) to occur?    4. Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?    5. Was the measurement of outcomes or effect at an appropriate level of precision?    6. Were other factors that could affect outcomes (e.g., confounders) measured or accounted for?    7. Were the measurements conducted consistently across units of observation, groups and time periods? | 7 | Select a Rating |
| 7.1 | Select a Rating |
| 7.2 | Select a Rating |
| 7.3 | Select a Rating |
| 7.4 | Select a Rating |
| 7.5 | Select a Rating |
| 7.6 | Select a Rating |
| 7.7 | Select a Rating |
| 1. **Was the statistical analysis appropriate for the study design and type of outcome indicators?**    1. Were statistical analyses adequately described the results reported appropriately?    2. Were correct statistical tests used and assumptions of test not violated?    3. Were statistics reported with levels of significance and/or confidence intervals?    4. Was there a clear description of subjects/units observed included in each analysis? If appropriate, was there a dose-response analysis?    5. Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?    6. Was clinical or pragmatic significance as well as statistical significance reported?    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). | 8 | Select a Rating |
| 8.1 | Select a Rating |
| 8.2 | Select a Rating |
| 8.3 | Select a Rating |
| 8.4 | Select a Rating |
| 8.5 | Select a Rating |
| 8.6 | Select a Rating |
| 8.7 | Select a Rating |
| 1. **Are conclusions supported by results with biases and limitations taken into consideration?**    1. Is there a discussion of findings?    2. Are biases and study limitations identified and discussed? | 9 | Select a Rating |
| 9.1 | Select a Rating |
| 9.2 | Select a Rating |
| 1. **Is bias due to study’s funding or sponsorship unlikely?**    1. Were sources of funding and investigators’ affiliations described?    2. Was there no apparent conflict of interest? | 10 | Select a Rating |
| 10.1 | Select a Rating |
| 10.2 | Select a Rating |
| **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/positive (+), or a majority of “No” answers for a minus/negative (-) rating.* | | |

Updated: January 2012