NYU SCHOOL OF GLOBAL PUBLIC HEALTH

Implementing Sustainable Evidence-based Interventions through Engagement (ISEE) Lab

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ENVISSION ASSESS 2.0

Risk of bias and quality assessment for implementation research outcomes

Version 2.0 • Implementing Sustainable Evidence-based Interventions through Engagement (ISEE) Lab • New York University School of Global Public Health

This tool is an internet-enabled Google Form ENVISSION ASSESS 2.0 is completed online, not on paper. It is hosted as a Google Form, so responses are captured and collated automatically for the review team. This document is a reference and planning companion — use it to see the full instrument in advance, to brief assessors, and to keep a record of what was asked. **Assessments themselves must be submitted through the live form. Open the form:** ENVISSION ASSESS 2.0 — Risk of Bias / Quality Assessment **Printable version of the form:** printform view An internet connection and a Google sign-in are required to submit. Questions marked * are required. Skip logic in the form routes you to one criteria set only, based on the study design you select — you will not see the other five.

Background Ryan N, Vieira D, Gyamfi J, et al. Development of the ASSESS tool: a comprehenSive tool to Support rEporting and critical appraiSal of qualitative, quantitative, and mixed methods implementation reSearch outcomes. *Implement Sci Commun.* 2022;3(1):34. https://pmc.ncbi.nlm.nih.gov/articles/PMC8959802/ A description for all sections can be found in the above referenced article, Table 2.

Use at least two assessors It is suggested that a minimum of two assessors assess each article to remove potential bias. Each assessor submits the form independently; disagreements are reconciled afterwards, with a third assessor resolving any that persist.

Section 1 — Article and outcomes

Assessor. Please enter: last name, first name.

1a. Author, Year (Smith, 2019)

1b. Title

2. Provide the IR-PICO research question, primary aim, or objectives. It is strongly recommended to state a research question.

3. Which current Proctor (2011) IR outcomes were addressed in this study? *(Check all that apply.)*

☐ **Implementation Research (in general)**	☐ **Appropriateness**	☐ **Fidelity**
☐ Acceptability	☐ Cost	☐ Penetration
☐ Adoption (uptake)	☐ Feasibility	☐ Sustainability
☐ Scalability		

Other: _____

4. IR-Service outcomes. *(Check all that apply.)*

☐ **Effectiveness**	☐ **Equity**	☐ **Safety**
☐ Efficiency	☐ Patient centeredness	☐ Timeliness
☐ Not addressed		

Other: _____

Section 2 — Risk of bias assessment

The list of assessment items was developed from existing tools including the StaRI checklist, the MMAT tool, and AMSTAR-2, implementation outcomes taxonomy and the FRAME framework. (Ryan, et al., 2022, p. 14)

How to score Provide a score of **0** or **1** to each criterion, where **1** indicates that the criterion was met and **0** indicates it was not met. If the criterion cannot be determined from what the study reports, select **2** for unsure — record the uncertainty rather than scoring it as a failure. For systematic reviews, **2** indicates unsure *or partially*. Use **Not applicable** where the criterion does not apply to the study. Report the criterion-level (domain-level) scores, not only a summary judgement: domain-level reporting identifies which methodological weakness recurs across the evidence, which a single band cannot. Then assign the composite 1–5 quality rating in Section 3.

5. Provide a brief description of the specific IR intervention.

2.1 Study design — select one

The live form branches from this answer. Complete only the criteria set that matches the design you select, then continue to the final comments in Section 3.

Table 1. Study design routing

	Study design	Go to
☐	1. Quantitative, RCT studies	Section 2.2
☐	2. Quantitative, non-RCT studies	Section 2.3
☐	3. Quantitative descriptive studies	Section 2.4
☐	4. Qualitative studies	Section 2.5
☐	5. Mixed methods studies	Section 2.6
☐	6. Systematic reviews	Section 2.7

2.2 Quantitative, RCT studies

*A clinical trial that involves at least one test treatment and one control treatment, concurrent enrollment and follow-up of the test- and control-treated groups, and in which the treatments to be administered are selected by a random process (PubMed, **MeSH** scope note).*

Criterion	0	1	2	Not applicable
Is randomization appropriately performed?	☐	☐	☐	☐
Are the groups comparable at baseline?	☐	☐	☐	☐
Are there complete outcome data?	☐	☐	☐	☐
Are outcome assessors blinded to the intervention provided?	☐	☐	☐	☐
Did the participants adhere to the assigned intervention?	☐	☐	☐	☐
Can the intervention described in this study be readily duplicated?	☐	☐	☐	☐

1a. Provide any additional comments regarding the quantitative, RCT approach of this article, or write “none”.

2.3 Quantitative, non-RCT studies

Non-randomized studies are defined as any quantitative studies estimating the effectiveness of an intervention or studying other exposures that do not use randomization to allocate units to comparison groups (Ryan, et al., 2022; see References, Higgins and Green, 2008).

Criterion	0	1	2	Not applicable
Are the participants representative of the target population?	☐	☐	☐	☐
Are measurements appropriate regarding both the outcome and intervention (or exposure)?	☐	☐	☐	☐
Are there complete outcome data?	☐	☐	☐	☐
Are the confounders accounted for in the design and analysis?	☐	☐	☐	☐
During the study period, is the intervention administered (or exposure occurred) as intended?	☐	☐	☐	☐

2a. Provide any additional comments regarding the quantitative non-RCT approach, or write "none".

2.4 Quantitative descriptive studies

Criterion	0	1	2	Not applicable
Is the sampling strategy relevant to address the research question?	☐	☐	☐	☐
Is the sample representative of the target population?	☐	☐	☐	☐
Are the measurements appropriate?	☐	☐	☐	☐
Is the risk of nonresponse bias low?	☐	☐	☐	☐
Is the statistical analysis appropriate to answer the research question?	☐	☐	☐	☐

3a. Provide any additional comments regarding the quantitative descriptive approach, or write "none".

2.5 Qualitative studies

"Qualitative research is an approach for exploring and understanding the meaning individuals or groups ascribe to a social or human problem" (Ryan, et al., 2022; see References, Creswell, 2013b).

Criterion	0	1	2	Not applicable
Is the qualitative approach appropriate to answer the research question?	☐	☐	☐	☐
Are the qualitative data collection methods adequate to address the research question?	☐	☐	☐	☐
Are the findings adequately derived from the data?	☐	☐	☐	☐
Is the interpretation of results sufficiently substantiated by data?	☐	☐	☐	☐
Is there coherence between qualitative data?	☐	☐	☐	☐

4a. Provide any additional comments regarding the qualitative approach, or write "none".

2.6 Mixed methods studies

Mixed methods (MM) research involves combining qualitative (QUAL) and quantitative (QUAN) methods.

Criterion	0	1	2	Not applicable
Is there an adequate rationale for using a mixed methods design to address the research question?	☐	☐	☐	☐
Are the different components of the study effectively integrated to answer the research question?	☐	☐	☐	☐
Are the outputs of the integration of qualitative and quantitative components adequately interpreted?	☐	☐	☐	☐
Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?	☐	☐	☐	☐
Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?	☐	☐	☐	☐

5a. Provide any additional comments regarding the mixed methods approach, or write "none".

2.7 Systematic reviews

*Based on AMSTAR-2: **https://amstar.ca/Amstar_Checklist.php*. *Please review the instructions to ensure understanding of the categories under review. Here, a score of 2 indicates unsure or partially.*

Criterion	0	1	2	Not applicable
Did the research questions and inclusion criteria for the review include the components of PICO or other research question framework?	☐	☐	☐	☐
Did the review include a comprehensive search strategy which can be replicated?	☐	☐	☐	☐
Did the review provide explicit inclusion criteria?	☐	☐	☐	☐
Did the review provide explicit exclusion criteria?	☐	☐	☐	☐
Did the review conduct a risk of bias or quality assessment?	☐	☐	☐	☐
If the review conducted a meta-analysis/synthesis, was the plan for analysis appropriate?	☐	☐	☐	☐
If the review conducted a meta-analysis/synthesis, did the review appropriately address heterogeneity?	☐	☐	☐	☐

6a. Provide any additional comments regarding the systematic review approach, or write "none".

Section 3 — Composite quality rating

After completing the criteria for the study design selected in Section 2.1, assign one composite rating for the study. This rating is what makes judgements comparable across designs, and it is the value carried forward into the risk-of-bias domain of the ENVISSION Certainty Rating.

Table 2. Composite quality rating

	Rating	Interpretation
☐	5	High quality, low risk of bias
☐	4	Good quality, low risk of bias
☐	3	Moderate quality, some concerns
☐	2	Low quality, high risk of bias
☐	1	Poor quality, high risk of bias

Record the rating per outcome, not per study alone A study can be well conducted for adoption and poorly conducted for fidelity. Where a study reports more than one implementation outcome, complete a rating for each outcome you intend to carry into the certainty rating, and note in the comments which outcome each rating refers to.

Section 4 — Final comments

Should data from this article be used in the introduction or discussion, etc.? Provide any additional comments relevant to this article.

Visualising your results RobVis is recommended for creating the risk-of-bias "traffic lights" and summary graphs. The live form links to the tool and its instructions.

Final comments:

Submit through the live form This document is a companion. To record an assessment, complete ENVISSION ASSESS 2.0 online.

References

Ryan, N., Vieira, D., Gyamfi, J., Ojo, T., Shelley, D., Ogedegbe, O., Iwelunmor, J., & Peprah, E. (2022). Development of the ASSESS tool: a comprehenSive tool to Support rEporting and critical appraiSal of qualitative, quantitative, and mixed methods implementation reSearch outcomes. *Implementation Science Communications*, *3*(1), 34. https://doi.org/10.1186/s43058-021-00236-4

Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., Griffey, R., & Hensley, M. (2011). Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health*, *38*(2), 65–76. https://doi.org/10.1007/s10488-010-0319-7

Shea, B. J., Reeves, B. C., Wells, G., et al. (2017). AMSTAR 2: a critical appraisal tool for systematic reviews. *BMJ*, 358, j4008. https://amstar.ca/Amstar_Checklist.php

Feedback For comments or suggestions to improve the ENVISSION ASSESS 2.0 tool, please submit the ENVISSION Toolkit: Suggestions for Improvement Form.