

Guidelines for Systematic Reviews

Revised January 2020

The American Journal of Occupational Therapy (AJOT) uses the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines as a basis for systematic reviews. Please refer to <u>http://www.prisma-statement.org/PRISMAStatement/Default.aspx</u> for details on the PRISMA guidelines. The PRISMA checklist is available at <u>http://www.prisma-statement.org/PRISMAStatement/Checklist.aspx</u>.

This document describes requirements for systematic reviews to be published in *AJOT*. Authors should direct questions about these requirements to the appropriate AOTA staff:

- Review content: AJOT Editor-in-Chief, ajoteditor@aota.org
- *Production:* Caroline Polk, <u>cpolk@aota.org</u>.

AUTHORS

Systematic reviews should be conducted and published by a team of two or more reviewers. Having only one reviewer is a risk-of-bias indicator for systematic reviews, and best practice methodology requires a multiple-reviewer approach to decrease risk of bias in the review.

TITLE

Provide a descriptive title for the systematic review. Identify the report as a systematic review, metaanalysis, or both. (PRISMA Item #1)

ABSTRACT/STRUCTURED SUMMARY

Provide a structured summary including, as applicable, background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; and systematic review registration number (if included). (PRISMA Item #2)

INTRODUCTION

Rationale

Describe the rationale for the review in the context of what is already known. (PRISMA Item #3)

Statement of Problem (formulation of the topic for the systematic review)

- What is the problem addressed by the focused question/topic?
- What significance does addressing this problem have for the following items (address areas as appropriate):
 - The clinical and community-based practice of occupational therapy
 - The education and training of occupational therapy students
 - Refinement, revision, or advancement of knowledge, theory, or research
 - Program development
 - Societal needs
 - Health care delivery and health policy
 - Coverage of payment for occupational therapy services at local, state, and national levels.

Background Literature

Keeping in mind the expectations and standards of a peer-reviewed scholarly journal, critically synthesize the background information and literature for the problem addressed. What is currently known about the



problem, and what is not yet known?

- Provide relevant definitions and descriptions of the intervention and approach, as needed.
- Discuss how this systematic review will contribute to our understanding or resolution of the problem addressed.

Objectives of the Systematic Review

- Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS), as appropriate. (PRISMA Item #4)
- If the focused question is part of a group of systematic reviews on a topic, state the importance of the focused question relative to the overall topic.

METHOD FOR CONDUCTING THE SYSTEMATIC REVIEW

In this section, describe the following:

- Whether a systematic review protocol exists and whether and where it can be accessed (e.g., URL of website). If available, provide registration information, including registration number. (PRISMA Item #5)
- Search strategy, including inclusion and exclusion criteria and screening procedures
 - List who conducted the search (e.g., independent librarian, librarian associated with author's institution).
 - Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, providing rationale. (PRISMA Item #6)
 - Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. (PRISMA Item #8)
- Procedures for identification and collection of articles
 - List databases and other information sources used to identify relevant studies (e.g., hand-searching reference lists and tables of contents, contacting content experts). Include dates of coverage of the search. (PRISMA Item #7)
 - State the process for selecting studies (i.e., screening, eligibility, criteria for inclusion in systematic review and, if applicable, criteria for inclusion in the meta-analysis). (PRISMA Item #9)
 - Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. (PRISMA Item #10)
 - List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. (PRISMA Item #11)
 - Describe method for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level) and how this information is to be used in any data synthesis. (Refer to the discussion of risk of bias in the Results section on p. 3 and to Table 1 and Table 2 on p. 4). (PRISMA Item #12)
 - State the principal summary measures (e.g., risk ratio, difference in means). (PRISMA Item #13).
 - Describe the method of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis. (PRISMA Item #14)
 - Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). (PRISMA Item #15)
 - Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, metaregression), if done, indicating which were pre-specified.* (PRISMA Item #16)

ΔΟΤΛ

RESULTS

- Provide the number of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage. Provide a flow diagram using the format shown in the Flow Diagram (**Figure 1**; p. 12). (PRISMA Item #17)
- For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. (PRISMA Item #18)
- Present data on risk of bias of each study and, if available, any outcome-level assessment (see item in Method section corresponding to PRISMA Item #12). (PRISMA Item #19)
- For all outcomes considered (benefits or harms), present for each study (1) simple summary data for each intervention group and (2) effect estimates and confidence intervals, using a forest plot as appropriate. (PRISMA Item #20)
- Present the main results of the review. If meta-analyses are included in the review, include for each, confidence intervals and measures of consistency. (PRISMA Item #21)
- Present results of any assessment of risk of bias across studies (see PRISMA Item #15). (PRISMA Item #22). Provide a table summarizing the risk of bias. Many methods of assessing risk of bias are available; examples are shown in **Table Templates 1, 2, and 3** starting on p. 7).
- Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, metaregression [see item * in Method section corresponding to PRISMA Item #16). (PRISMA Item #23)

To synthesize the articles and create the results, do the following:

- Organize studies according to themes. Organize and group studies within the themes, rather than report on results of individual studies.
- Synthesize by answering the question, "What do we know, from an evidence-based perspective, about specific dimensions of the focused question?" The synthesis must reflect the strength of the findings in relation to the *types of study design (Level)* and the *methodological weaknesses present (biases and study limitations)*. Although there can be study limitations at all levels, please keep in mind that results from a Level 1A, 1B, 2A, 2B, 3A, or 3B study will provide stronger evidence than results from a Level 4 or 5 study. The Levels of Evidence are presented in **Table 1** (p. 4); in addition, the evidence within a theme should be described according to the strength of the evidence (level of certainty); see **Table 2** (p. 4).
- Include a table summarizing the evidence generated from each study. An example is shown in **Table 3** (p. 6); also refer to **Table Template 4** and the **Guidelines** on pp. 9–11.

DISCUSSION, LIMITATIONS, AND CONCLUSIONS

- Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, educators, clients, and policymakers). (PRISMA #24)
- Discuss limitations at the study, outcome level (e.g., risk of bias), and review level (e.g., incomplete retrieval of identified research, reporting bias). (PRISMA #25)
- Provide a general interpretation of the results in the context of other evidence and implications for future research. (PRISMA #26)

This section is an opportunity for authors to interpret the evidence synthesis (results of the review) and to develop implications for practice, education, or future research. End this section of the article with a response to the following questions:

• Do the findings warrant further research, and are there gaps that need to be filled? If yes, what kind of questions and directions?



- What are the strengths and limitation of the systematic review?
- What principles or fundamental conclusions can be applied to practice, education, and research from the review?
- Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. (PRISMA #27)

Other

Authors of systematic reviews to be published in *AJOT* should refer to the *Guidelines for Contributors to AJOT*, which are updated each year. The 2019 edition is available at

<u>https://doi.org/10.5014/ajot.2019.73S205;</u> updates to the guidelines that occur between editions are provided at <u>https://ajot.aota.org/ss/authors.aspx</u>.

Table 2	1. Levels of Evidence						
Level	Type of Evidence						
1A	Systematic review of homogeneous RCTs (similar population, intervention, etc.) with or						
	without meta-analysis						
1B	Well-designed individual RCT (Not a pilot or feasibility study with a small sample size)						
2A	Systematic review of cohort studies						
2B	Individual prospective cohort study, low-quality RCT (e.g., <80% follow-up or low number of						
	participants; pilot and feasibility studies); ecological studies; and two-group, nonrandomized						
	studies						
3A	Systematic review of case-control studies						
3B	Individual retrospective case-control study; one-group, nonrandomized pre-posttest study;						
	cohort studies						
4	Case series (and low-quality cohort and case-control study)						
5	Expert opinion without explicit critical appraisal						
Note. R	<i>Note</i> . RCT = randomized controlled trial.						
From O	CEBM Levels of Evidence Working Group. (2011). The Oxford Levels of Evidence 2. Oxford Centre for						
Evidenc	e-Based Medicine. http://www.cebm.net/index.aspx?o=5653						
See also	https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/						

Table 2. Str	Table 2. Strength of Evidence (Level of Certainty)								
Strength	Description								
Strong	 Two or more Level 1A/B studies The available evidence usually includes consistent results from well-designed, well- 								
	conducted studies. The findings as strong and they are unlikely to be strongly called into question by the results of future studies.								
Moderate	 At least one Level 1A or Level 1B high-quality study or multiple moderate-quality studies (Level 2A/B, Level 3A/B, etc.) The available evidence is sufficient to determine the effects on health outcomes, but confidence in the estimate is constrained by such factors as: The number, size, or quality of individual studies. Inconsistency of findings across individual studies. 								
	As more information (other research findings) becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion related to the usefulness of the intervention.								
Low	• Small number of low-level studies, flaws in the studies, etc.								



Table 2. Strength of Evidence (Level of Certainty)								
Strength	Description							
	 The available evidence is insufficient to assess effects on health and other outcomes of relevance to occupational therapy. Evidence is insufficient because of The limited number or size of studies; Important flaws in study design or methods; Inconsistency of findings across individual studies; or Lack of information on important health outcomes. 							
	More information may allow estimation of effects on health and other outcomes of relevance to occupational therapy.							
Note. The str	ength of the evidence is based on the guidelines of the U.S. Preventive Services Task Force							
(https://www	y.uspreventiveservicestaskforce.org/Page/Name/grade-definitions).							



Table 3. Sample Evidence Table										
Table X. [Title]									
Author/Year	Level of Evidence Study Design Risk of Bias	Participants Inclusion Criteria Study Setting	Intervention and Control Groups	Outcome Measures	Results					
Cognitive Inter	rventions									
Law et al. (2014) [Include DOI from reference list]	Level 1B RCT <i>Risk of Bias</i> Moderate	Participants $N = 83$ (M age, 73.8 yr;60% female).Inclusion CriteriaCommunity-dwelling adults ≥ 60 yr old with mildcognitive impairmentIntervention SettingOutpatient clinic	Intervention 1: FcTSim Program ($n = 43$) 13 sessions in 10 wk, facilitated by an occupational therapist. All sessions began with light stretching, followed by a 30-min core FcTSim and a cool-down. Intervention 2: Active Cognitive Training ($n = 40$) 13 session, 10-wk program facilitated by an OT and an OTA. Each session included 30 min computer-based cognitive training (visual searching, forward- backward digit recall and calculation) and 30 min cognitive strategy training. Each session was supplemented with paper-and-pencil home assignments.	 <i>Cognitive</i> Neurobehavioral Cognitive Status Examination Trail-Making Test Chinese Version Verbal Learning Test <i>IADLs</i> Lawton Instrumental Activities of Daily Living 	Significant Findings The FcTSim group showed significantly greater improvement than the cognitive training group in general cognitive functions, memory, executive function, functional status, and everyday problem-solving ability. Improvements were sustained at 6-mo follow-up. <i>Nonsignificant Findings</i> None					
McDaniel et al. (2014)	Level 1B RCT <i>Risk of Bias</i> Low	Participants N = 96 (M age, 65 yr; 65% female). Inclusion Criteria Community-dwelling adults aged 55 to 75 yr Intervention Setting Outpatient clinic	Intervention 1: Cognitive Training $(n = 23)$ 6-mo home exercise program. At Month 5, began the cognitive-training intervention.Intervention 2: Exercise $(n = 24)$ Aerobic exercise on stationary bike or treadmill conducted onsite at the community center, $3x/wk$ for 6 moIntervention 3: Combined Cognitive Training and Exercise $(n = 24)$ Control Group $(n = 25)$ 6-mo low-intensity home exercise program with 8-wk program of face-to-face health education sessions.	 Activity/Function Cooking Breakfast (computer task) Virtual Week (computerized) Memory Memory for Health Information (Part 1 and 2) Stroop Part 1, Logical Memory Immediate 	Significant Findings None Nonsignificant Findings Cognitive training, either alone or in combination with 6 mo aerobic exercise, did not significantly improve Cooking Breakfast or Memory for Health Information.					

Table Templates

	Table Template 1. Risk-of-Bias Table for Systematic Reviews (AMSTAR2)												
Citation	All components of PICO addressed [1]	"a priori design" included? [2]	Explanation of the selection of the study designs for inclusion in the review? [3]	Compre- hensive literature search performed? [4]	Authors perform study selection and data extraction in duplicate? [5-6]	List of excluded studies provided? [7]	Authors describe the included studies in adequate detail? [8]	Quality of studies (risk of bias) assessed and docu- mented? [9]	Authors report on the sources of funding for the studies included in the review? [10]	Authors account for risk of bias in primary studies when inter- preting/ discussing the results of the review? [13]	Satisfactory explanation for, and discussion of, any he- terogeneity observed in the results of the review? [14]	Authors report any potential sources of conflict of interest, including any funding they received for conducting the review? [16]	Overall risk of bias assessment (low, moderate, high risk)
Author (year)	+	+	_	_	_	_	+	+	+	+	+	_	М
Note. Key =	- Yes (+), No	(–), Not sure	(?), Not appli	cable (NA). S	coring for ov	erall risk-of-l	bias assessme	nt is as follov	vs: 0–3 minus	es, low risk o	f bias (L); 4–	6 minuses, mo	oderate risk

of bias (M); 7–9 minuses, high risk of bias (H).

Citation. Table format adapted from Shea, B. J., Reeves, B. C., Wells, G., Thuku, M., Hamel, C. Moran, J., . . . Henry, D. A. (2017). AMSTAR 2: A critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*, *358*, j4008. <u>https://doi.org/10.1136/bmj.j4008</u>



Table Template 2. Risk-of-Bias Table: Randomized Controlled Trial (RCT) and Non-RCT												
	Selection	n Bias (risk of bia	as arising from	Performance Bias (effect of					Reporting			
	randomization process)			assignment to intervention)		Detectio	Detection Bias		Bias			
							Blinding of		Selective			
							Outcome		Reporting			
			Baseline				Assessment:		(results			
		Allocation	differences				Objective	Incomplete	being	Overall risk-		
		Concealment	between		Blinding of	Blinding of	Outcomes	Outcome	reported	of-bias		
		(until	intervention	Blinding of	Study	Outcome	(assessors	Data (data for	selected on	assessment		
	Random	participants	groups (suggest	Participants	Personnel	Assessment:	aware of	all or nearly	the basis of	(low,		
	Sequence	enrolled and	problem with	During the	During the	Self-reported	intervention	all	the	moderate,		
Citation	Generation	assigned)	randomization?)	Trial	Trial	outcomes	received?)	participants)	results?)	high risk)		
Cooper et al. (2012)	+	+	_	_	_	_	+	+	+	М		

Note. Categories for risk of bias are as follows: Low risk of bias (+), unclear risk of bias (?), high risk of bias (–). Scoring for overall risk of bias assessment is as follows: 0–3 minuses, low risk of bias (L); 4–6 minuses, moderate risk of bias (M); 7–9 minuses, high risk of bias (H).

Citation. Table format adapted from Higgins, J. P. T., Sterne, J. A. C., Savović, J., Page, M. J., Hróbjartsson, A., Boutron, I., . . . Eldridge, S. (2016). A revised tool for assessing risk of bias in randomized trials. *Cochrane Database of Systematic Reviews 2016*, Issue 10 (Suppl. 1), 29–31. <u>https://doi.org/10.1002/14651858.CD201601</u>

Table Template 3. Risk of Bias for Before–After (Pre–Post) Studies With No Control Group

							Outcome			Statistical	Outcome	
							measures			methods	measures	
					Sample		pre-			examine	were	
		Eligibili-			size	Interven-	specified,		Loss to	changes in	collected	Overall risk
		ty or	Participants		appro-	tion clearly	defined,	Assessors	follow-	outcome	multiple	of bias
	Study	selection	representa-		priate for	described	valid/	blinded to	up after	measures	times	assessment
	question	criteria	tive of real-	All eligible	confi-	and	reliable, and	participant	baseline	from before	before and	(low,
	or object-	clearly	world	participants	dence in	delivered	assessed	exposure to	20% or	to after	after inter-	moderate,
Citation	tive clear	described	patients	enrolled	findings	consistently	consistently	intervention	less	intervention	vention	high risk)
Holm et al. (2015)	Y	NR	Ν	NR	NR	Ν	Y	Ν	Ν	Y	Ν	М

Note. Y = yes; N = no; NR = not reported. Scoring for overall risk of bias assessment is as follows: 0-3 N, Low risk of bias (L); 4-8 N, Moderate risk of bias (M); 9-11 N, High risk of bias (H).

Citation. Table format adapted from National Heart Lung and Blood Institute. (2014). *Quality assessment tool for before–after (pre–post) studies with no control group*. Retrieved from https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools

Important: Refer to Table 3 on p. 3 and to the Instructions and Guidelines on pp. 10 and 11 for additional guidance on creating evidence tables.

Table Template 4. Format for Evidence Tables										
Table X. [Title]		-		_	-					
Author/Year	Level of Evidence Study Design Risk of Bias (Quality Assessment)	Participants Inclusion Criteria Study Setting	Intervention and Control Groups	Outcome Measures	Results (Including significance of findings)					
[Theme]										
Green, Brown, Blue, Black, & White (2001) https:/doi.org/ [If 6 or more authors, list first author and "et al." followed by the date. Provide DOI for all studies.]	Level of evidence [Level 1A or 1B, 2A or 2B,, etc.] Study design [RCT, systematic review, etc.] <i>Risk of Bias</i> [low, moderate, high]	Participants N = [older adults, youth, children] (<i>M</i> age, yr [or mo, or days]; 60% female). Inclusion Criteria [list] Intervention Setting [list]	Intervention [Summarize each intervention; include <i>n</i> . Label as Intervention 1, 2, etc., for multiple interventions.] Control [Summarize. Include <i>n</i> .]	 [List measures appropriate to answering the focused question] <i>Heading</i> Measure Measure 	Significant Findings [List results of the study appropriate to answering the focused question that are statistically significant.] [List relevant study findings that are NOT statistically significant.]					
					Nonsignificant Findings					
Note. [Define all abbre	<i>Note.</i> [Define all abbreviations here; e.g., IADLs = independent activities of daily living; RCT = randomized controlled trial].									



Instructions for Creating Evidence Tables

Author/Year

• List the last names of the authors followed by the year of publication (e.g., Gish, Staplin, & Perel, 1999), followed by the DOI from the reference citation.

Level of Evidence/Study Design/Risk of Bias

- List the level of evidence (Level 1A, Level 2B, etc.) for the study.
- Identify the study design.
- Indicate the risk of bias (low, moderate, high). This information comes from the appropriate risk-ofbias tables (based on study design).

Study Participants/Inclusion Criteria/Study Setting

- List the number of study participants. Include percentage female and the mean age or age range, if included. If the study has more than one group, list the number in each group.
- List the inclusion criteria.
- Identify the intervention setting.

Intervention and Control Groups

- List only the intervention and control groups relevant to answering the focused question.
- Provide a *brief* description of what the interventions entail; many titles do not provide enough information to have a general understanding of the intervention.
- Include the number of participants in each group (n = ?).

Outcome Measures

- Include the skill or activity being assessed (e.g., ADLs), and then list the name of the assessments used (e.g., Barthel).
- *Note.* Outcomes are the variables or issues of interest to the researcher. They represent the product or results of the intervention or exposure. Many studies include several outcome measures. For the purpose of the Evidence Table, we include only those measures relevant to answering the focused question.

Results

- List only the results of the study that are appropriate to answering the focused question.
- Indicate whether the results are statistically significant or not.



Editorial and Formatting Guidelines for Evidence Tables

Systematic reviews and the related tables will be edited to conform to the format described in this document. Refer to the table templates on the previous pages for guidance. Authors should not vary from the format. Adherence to the prescribed format will save time in production, avoid rewrites, and result in a higher quality product.

Important: The formats of systematic reviews and evidence tables change over time. Previously published evidence tables and systematic reviews are NOT a guideline for format and style. Please consult AOTA staff (ajotproduction@aota.org) with any questions concerning format and style.

Different studies have different levels of complexity (e.g., multiple interventions or control groups), and study descriptions may vary slightly and require additional information for clarity. The goal is for evidence tables to be consistent in content and style.

General formatting guidelines are as follows:

- List the studies in alphabetical order by first author. If 6 or more authors, list first author and "et al." followed by the date. Include the full reference citation in the accompanying manuscript or article.
- In the reference list, place a * next to each study included in the systematic review.
- Abbreviate names of assessments and programs when they are commonly known by an abbreviation or acronym (e.g., AMPS, SF–36). Define all abbreviations in the table note rather than in the body of the table.
- There is no need to provide references for assessments listed as outcome measures, but if an assessment is discussed in the article that accompanies the table, a reference for that assessment should be provided in the article's reference list.
- All text in a given table column should have a consistent structure (e.g., bulleted lists, phrases). Brevity is key.
- Separate phrases and sentences with a line space (see above sample).
- Use bullets when there are multiple items in a list.
- Format levels of evidence to match the Oxford levels (Level 1A, Level 3B, etc.).
- Use <, >, \leq , \geq , /wk, /yr, and other common abbreviations.

Figure 1. Flow Diagram

It is important to provide transparency in the review process. One way to document the review process is by using the following flow diagram. Authors should include boxes below, as appropriate.



From "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement," by D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman; The PRISMA Group, 2009, *PLoS Med* 6(6): e1000097. http://dx.doi.org/10.1371/journal.pmed1000097