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Appendix F.3: Inclusion and Exclusion Criteria

Inclusion Criteria

Studies were considered for inclusion for review, if the following criteria were met:

- English language literature,
- Date of publication between January 1, 1995 and June 30, 2007,
- Original research reports only (reviews, meta-analyses, structured reviews, previously published physical activity guidelines, and recommendations to be retrieved and stored for background information for use by Physical Activity Guidelines Advisory Committee [PAGAC]),
- Peer-reviewed literature only,
- Main antecedent or exposure variable is physical activity or exercise, and
- Main health outcome variable or risk factor is clearly described and fits into one of our health outcome categories.

Exclusion Criteria

The purpose of the Exclusion/Inclusion flow process was to classify efficiently and accurately references for the abstraction process. The overall process is a 2-phased system: Studies of physical activity and a diagnosable health outcome were abstracted during Phase 1, followed by studies of physical activity and risk factors for the health outcomes, possibly abstracted at a later date (Phase 2), if requested by the PAGAC. Abstracts that were initially excluded were coded using a system that will allow for later retrieval, should it be necessary.

The goal of the Exclusion/Inclusion process was to code references identified from the “Physical Activity AND Health Outcome” search strategy (see description of Search Strategy for specific search terms) into mutually exclusive categories, indicating if they will be included or excluded for abstraction. Upon initial review, the abstract was screened by a team leader and assigned one of the following Exclusion/Inclusion codes:

1 = Yes (Meets screening criteria, will be abstracted);

2 = No (Does not meet screening criteria, will be excluded from further review); or

3 = Phase 2 (Does not meet screening criteria for inclusion in Phase 1 abstraction process, but does meet screening criteria for Phase 2 abstraction process).

Inclusion/Exclusion Coding System

As abstracts were reviewed for exclusion/inclusion, team leaders worked through the following hierarchical flow system. If an abstract was “stopped” at any point in the flow process, then the appropriate exclusion code was entered into Reference Manager in the user-defined “Abstract” cell. The flow system is described below.

If the reference was coded “1” (YES) or “3” (Phase 2) for abstraction, the reviewer also coded the “Age group” and “Health outcome” cells in Reference Manager.

If one team leader was unsure how to triage an abstract, he/she would consult with another team leader for their input.

The Flow Process

In the first step of the flow process, the reviewer will determine if the abstract contains an appropriate measure of physical activity. If YES, then the reviewer will move on to step 2. If NO, the reviewer will enter one of the following exclusion codes into Reference Manager: 11 = Missing physical activity; 12 = Single acute bout of exercise; 13 = Specific therapeutic exercise (Kegel, inspiratory muscle training); 14 = Single measure of physical fitness (cardiovascular fitness, strength, flexibility); 15 = Not primary exposure variable or used solely as confounding variable; 16 = Sedentary behavior (TV viewing, computer games, sleep, other); or 17 = Other.

Definitions of the exclusion codes and examples to illustrate each of the codes are provided below.

<p>11 = Missing physical activity: Definition: When the abstract does not contain relevant physical activity or exercise as listed in the physical activity section of the search strategy. For example, an abstract might state that the purpose is to examine “associations between participation in different types of mentally stimulating leisure activities and status as Alzheimer’s disease (AD).” In this case, leisure activities are mental activities (games and puzzles) – not activities with large muscle movement (i.e., physical activity) and would therefore not be eligible.</p>
<p>12 = Single, acute bout of exercise: Definition: This represents an acute exposure to an exercise or physical activity session, such as a maximal exercise stress test, a walking test, or a single session of weight lifting exercises. Health-related responses often will occur shortly (minutes or hours) after the exposure. For example, in a study of the effects of resistance exercise on postural control mechanisms in 21 older adults, participants performed three sets of 10-12 repetitions for six resistance exercises for the lower extremity until fatigue. Immediately after exercise, postural stability was reduced.</p>
<p>13 = Specific therapeutic exercise (Kegel, inspiratory muscle training): Definition: Where physical activity has the purpose to treat or rehabilitate a health condition. For example, a study that evaluates a walking program incorporating real-time biofeedback to reduce asymmetric limb loading after total hip arthroplasty (THA). In this case, the treadmill walking program is a therapeutic exercise to help persons with a THA achieve a more symmetric gait.</p>
<p>14 = Single measure of physical fitness (cardiovascular fitness, strength, flexibility): Definition: Where the measure of physical activity is based only on physical fitness measures (single or combined variables). For example, a study that examines the combined effects of motor speed and knee extension strength on risk of fall-related bone fractures in elderly individuals over a 10-year period. In this case, motor speed and knee extension strength are measures of physical fitness.</p>

<p>15 = Not primary exposure variable or used solely as a confounding variable: Definition: Where physical activity is used as a secondary variable only in an analysis. For example, in a study of smoking status and cardiovascular disease, physical activity may be included as a confounding variable. If physical activity is not the primary exposure of interest, the study was excluded.</p>
<p>16 = Sedentary behavior (TV viewing, computer games, sleep, other): Definition: Where the measure of physical activity is characterized by activities that require little energy expenditure. For example, in a study that examines self-reported sleep and nap habits and risk of falls and fractures in older women, this exposure (sleeping and napping) requires little energy expenditure.</p>
<p>17 = Other: Definition: If the reason for exclusion does not fall into one of the categories described above, enter this code. For example, a study in which the purpose was to test the ability of the Transtheoretical Model to predict exercise stage transition of individuals in a large, untreated-population-based, random sample of adults (18-65 years of age) over two consecutive time periods.</p>

Once an eligible abstract is passed to the second step, the reviewer will next determine if the health outcome is appropriate for abstraction. We abstracted in two phases, where “Phase 1” consisted of the diagnosable or so-called “hard” health outcomes, and “Phase 2” consisted of the “risk factors” for the Phase 1 outcomes. If the health outcome was deemed appropriate for Phase 1 abstractions, the reviewer moved to step 3. If not, the reviewer entered one of the following exclusion codes into Reference Manager: 21 = Missing health outcome; 22 = Inappropriate health outcome (see Phase 1 health outcome list); 23 = Phase 2 health outcome (see Phase 2 health outcome list); 24 = Study of physical activity correlates; or 25 = Other.

<p>21 = Missing health outcome Definition: If the abstract does not include a Phase 1 or Phase 2 health outcome, enter this code.</p>
<p>22 = Inappropriate health outcome (see Phase 1 health outcome list) Definition: If the outcome described in the abstract is not a Phase 1 or Phase 2 outcome, enter this code.</p>
<p>23 = Phase 2 health outcome (see Phase 2 health outcome list) Definition: If the outcome described in the abstract is a Phase 2 outcome, enter this code.</p>
<p>24 = Study of physical activity correlates Definition: If the primary purpose of the study is to examine characteristics associated with physical activity (i.e., correlates), enter this code.</p>
<p>25 = Other Definition: If the reason for exclusion does not fall into one of the categories described above, enter this code.</p>

In the third step, the reviewer will determine if the article is of an appropriate format to abstract. If not, the reviewer will enter one of the following exclusion codes into Reference Manager: 31 = Review, meta-analysis, no abstract; 32 = Case report; or 33 = Other.

<p>31 = Review, meta-analysis, no abstract Definition: If the abstract is a review article, meta-analysis, or does not have an abstract, enter this code.</p>
<p>32 = Case report Definition: If the abstract is a case report (single case) or case series (multiple cases), enter this code.</p>
<p>33 = Other Definition: If the reason for exclusion does not fall into one of the categories described above, enter this code. For example: a study that examines the contribution of infant and caregiving conditions to the quantity of focused exploration of toys for 8-month-old infants.</p>

<p>34 = Injury as health outcome with no variation in the physical activity exposure</p> <p>Definition: If there is no variation in physical activity exposure, enter this code. For example, a study of injuries among rock climbers is coded as “exclude” code “34,” because there is no variation in the physical activity exposure of rock climbing.</p>
<p>35 = Physical activity as health outcome in a cross-sectional study</p> <p>Definition: In cross-sectional studies of physical activity and a health outcome (e.g., BMI), if physical activity is the outcome (dependent) measure in the analysis, enter this code. For example, mean minutes of leisure time physical activity are reported for two categories of BMI (overweight and obese).</p>
<p>41 = Study design or study characteristics are not acceptable for Phase 2 abstraction as designated by the Federal Advisory Committee</p> <p>Definition: Phase 2 abstraction criteria designated by a Federal Advisory Committee subcommittee. For example, a subcommittee may elect to abstract studies of a specific study design (e.g., randomized, controlled trial) or of studies with specific study characteristics (e.g., sample size).</p>
<p>50 = No relevant Phase 2 mental health outcomes</p> <p>Definition: Paper does not include a relevant phase 2 mental health outcome</p>
<p>51 = Phase 2 health outcome is sleep</p> <p>Definition: Paper includes sleep as the main health outcome</p>
<p>52 = Phase 2 health outcome is pain</p> <p>Definition: Paper includes pain as the main health outcome</p>
<p>53 = Phase 2 health outcome is self-esteem, self-efficacy, or self-concept</p> <p>Definition: Paper includes self-esteem, self-efficacy, or self-concept as a main health outcome</p>
<p>54 = Phase 2 health outcome is schizophrenia or other psychoses</p> <p>Definition: Paper includes schizophrenia or other psychoses as a main health outcome</p>
<p>55 = Phase 2 health outcome is anger</p> <p>Definition: Paper includes anger as the main health outcome</p>
<p>56 = Phase 2 health outcome is fatigue</p> <p>Definition: Paper includes fatigue as the main health outcome</p>
<p>57 = Phase 2 health outcome is well-being, quality of life, life satisfaction, distress, or stress</p> <p>Definition: Paper includes well-being, quality of life, life satisfaction, distress, or stress as the main health outcome</p>
<p>58 = Other phase 2 mental health outcome</p> <p>Definition: Paper includes a non-Phase 2 mental health condition as the main health outcome</p>

Once the reviewer determines that an article is NOT excluded for inappropriate physical activity, health outcome, or format, the article is coded as 1= “YES” in the Abstraction cell of Reference Manager. The reviewer will also need to code for Age Group (1 = Youth; 2 = Adult; 3 = Older Adult; or 4 = Age Unknown) and Health Outcome Categories (1 = Cardiovascular/Respiratory Health; 2 = Metabolic Health; 3 = Musculoskeletal Health; 4 = Cancer; 5 = Functional Health; 6 = Mental Health; 7 = All-Cause Mortality; and 8 = Adverse Events/Risk of Physical Activity).

If multiple health outcomes are found in the paper, the reviewer will code for the most prevalent or most relevant.

Table 1 provides exclusion codes for the initial review of references.

Table 1. Exclusion Codes* for Initial Review of References: *Physical Activity Guidelines for Americans***1. Physical Activity**

Exclusion Code	Definitions	Abstraction Code
11	(1) Missing physical activity	2 (No)
12	(2) Single acute bout of exercise	2 (No)
13	(3) Specific therapeutic exercise (Kegel, inspiratory muscle training)	2 (No)
14	(4) Single measure of physical fitness (cardiovascular fitness, strength, flexibility)	2 (No)
15	(5) Not primary exposure variable or used solely as confounding variable	2 (No)
16	(6) Sedentary behavior (TV viewing, computer games, sleep, other)	2 (No)
17	(7) Other	2 (No)

2. Health Outcome

Exclusion Code	Definitions	Abstraction Code
21	(1) Missing health outcome	2 (No)
22	(2) Inappropriate health outcome (see Phase 1 health outcome list)	2 (No)
23	(3) Phase 2 health outcome (see Phase 2 health outcome list)	3 (Phase 2)
24	(4) Study of physical activity correlates	2 (No)
25	(5) Other	2 (No)

3. Inappropriate Format

Exclusion Code	Definitions	Abstraction Code
31	(1) Review, meta-analysis, no abstract	2 (No)
32	(2) Case report	2 (No)
33	(3) Other (includes ineligible age groups)	2 (No)
34	(4) Health outcome with no variation in the physical activity exposure or no physical activity dose available	2 (No)
35	(5) Physical activity as health outcome in a cross-sectional study	2 (No)

Phase 2 Abstraction Criteria From Federal Advisory Committee

Exclusion Code	Definitions	Abstraction Code
41	(1) 41 = Study design or study characteristics are not acceptable for Phase 2 abstraction as designated by the Federal Advisory Committee	2 (No)

Table 1. Exclusion Codes* for Initial Review of References: *Physical Activity Guidelines for Americans* (continued)**Phase 2 Abstraction Codes Specific to Mental Health Subcommittee**

Exclusion Code	Definitions	Abstraction Code
50	No relevant Phase 2 mental health outcomes	2 (No)
51	Phase 2 health outcome is sleep	2 (No)
52	Phase 2 health outcome is pain	2 (No)
53	Phase 2 health outcome is self-esteem, self-efficacy, or self-concept	2 (No)
54	Phase 2 health outcome is schizophrenia or other psychoses	2 (No)
55	Phase 2 health outcome is anger	2 (No)
56	Phase 2 health outcome is fatigue	2 (No)
57	Phase 2 health outcome is well-being, quality of life, life satisfaction, distress, or stress	2 (No)
58	Other phase 2 mental health outcome	2 (No)

*There are exceptions to this model. Studies with an appropriate health outcome and with physical activity classified as shown below will be included and coded:

If the study:

- (1) Is an experimental study where physical activity + diet (non-drug) is a treatment arm.
- (2) Is an experimental study where the treatment arms are able to test the singular effect of physical activity. For example, in a study that included two treatment arms: (1) Physical Activity + Treatment X versus (2) Treatment X.
- (3) Studies where the physical activity exposure is based on group membership (not individually assessed — e.g., occupational category; athletic/sport participation, etc.) will be included.