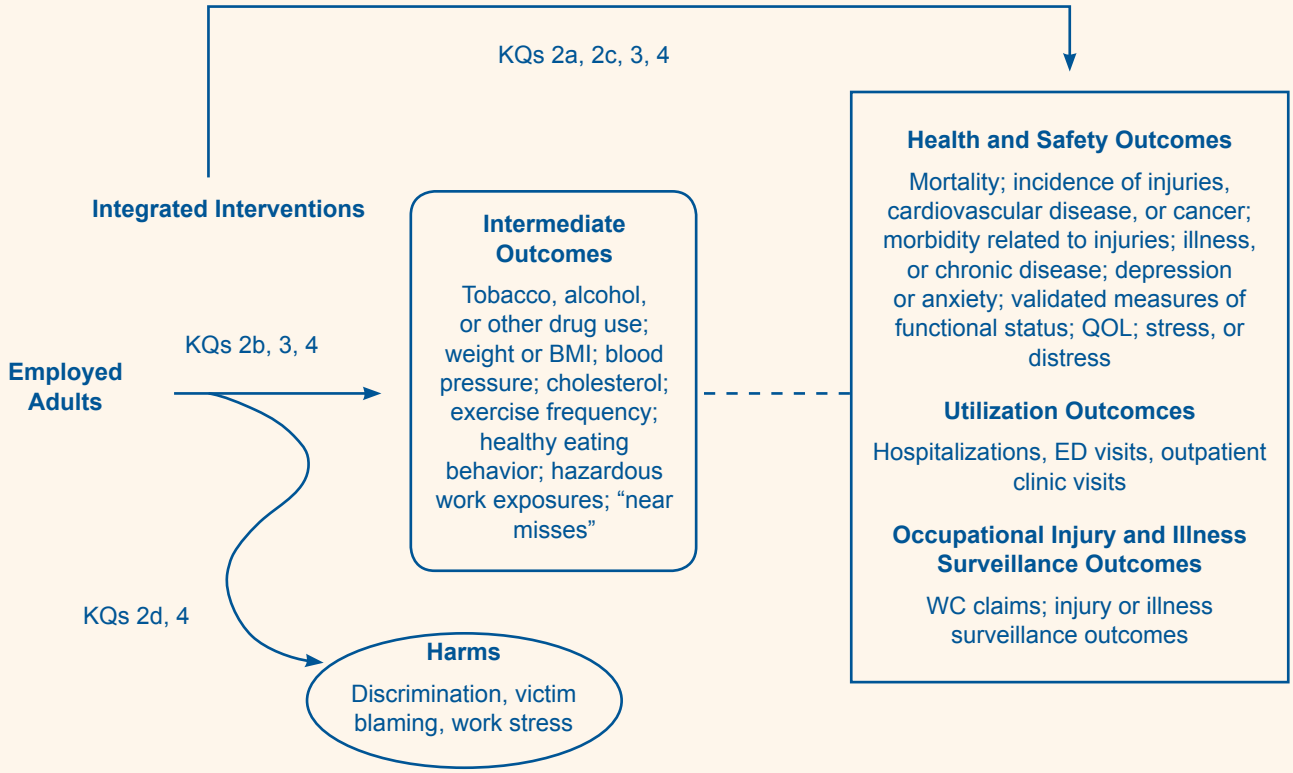
Figure A. Analytic framework for Total Worker Health interventions



BMI = body mass index; ED = emergency department; KQ = Key Question; QOL = quality of life; WC = workers' compensation.

Methods

Topic Refinement and Protocol Review

The NIH P2P Working Group provided the initial KQs. The RTI International–University of North Carolina Evidence-based Practice Center (EPC) further refined them and incorporated guidance from a Technical Expert Panel into the final research protocol. It was posted on the Agency for Healthcare Research and Quality (AHRQ) Web site on May 26, 2015, at www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2085.

Literature Search Strategy

Search Strategy

We searched MEDLINE®, the Cochrane Library, the Cochrane Central Trials Registry, and PsycINFO® from January 1, 1990, to September 21, 2015. An experienced research librarian used a predefined list of search terms and medical subject headings (MeSH).

We searched for unpublished studies relevant to this review using ClinicalTrials.gov and Academic Search™ Premier; on our behalf, the AHRQ Scientific Resource Center solicited scientific information packages via Federal Register notices or informational requests. We received a bibliography from NIOSH listing studies relevant to the TWH program. We used

Data Abstraction

We developed a template for evidence tables using the PICOTS framework and abstracted relevant information into them using Microsoft® Excel. We recorded characteristics of study populations, interventions, comparators, settings, study designs, methods, and results. Six trained members of the team participated in the data abstraction. One reviewer initially abstracted the relevant data from each included article; a second member of the team reviewed each data abstraction against the original article for completeness and accuracy.

Risk-of-Bias Assessment

To assess the risk of bias (internal validity) of studies eligible for KQ 2, we used predefined criteria based on the AHRQ "Methods Guide for Effectiveness and Comparative Effectiveness Reviews" (Methods Guide). These criteria included questions to assess selection bias, confounding, performance bias, detection bias, and attrition bias (i.e., those about adequacy of randomization, allocation concealment, similarity of groups at baseline, masking, attrition, use of intention-to-treat analysis, method of handling dropouts and missing data, reliability and validity of outcome measures, and treatment fidelity).[17] Appendix C of the full report lists the specific questions used for evaluating the risk of bias of included studies eligible for KQ 2 (i.e., studies with a concurrent control group). Both the questions and responses are shown in tables along with a rationale for all ratings that were either high or medium risk of bias.

In general terms, results from a study with low risk of bias are considered to be valid. A study with moderate risk of bias is susceptible to some risk of bias but probably not enough to invalidate its results. A study assessed as high risk of bias has significant risk of bias (e.g., stemming from serious errors in design, conduct, or analysis) that may invalidate its results. To assess publication bias, we looked for evidence of unpublished literature through searches of gray literature (ClinicalTrials.gov). We also reviewed, when available, the original protocols for included trials to assess for selective outcome reporting.

We determined the risk-of-bias ratings using the responses to all questions assessing the various types of bias listed here. To receive a low risk-of-bias rating, we required favorable responses to most questions, and any unfavorable responses had to be relatively minor. We gave high risk-of-bias ratings to studies that we determined to have a major methodological shortcoming in one or more categories based on our qualitative assessment. Common methodological shortcomings contributing to high ratings were high rates of attrition or differential attrition and inadequate methods used to handle missing data.

Two independent reviewers assessed the risk of bias for each study. Disagreements between reviewers were resolved by discussion and consensus or by consulting a third member of the team.

Data Synthesis

Quantitative synthesis (meta-analysis) was not appropriate to this topic, given the heterogeneity in the included populations, interventions, comparators, outcomes, work settings and geographic settings of included studies. We did all analyses qualitatively, based on our reasoned judgment of similarities in interventions, measurement of outcomes, and homogeneity of occupational groups.

Strength of the Body of Evidence

We graded the SOE based on the Methods Guide.[18] The EPC approach incorporates five key domains: study limitations, directness, consistency, precision of the evidence, and reporting bias.

Grades reflect the strength of the body of evidence to answer each KQ. A grade of high SOE indicates that we have high confidence that the evidence reflects the true effect. Moderate SOE indicates that we have moderate confidence that the evidence reflects the true effect. Low SOE suggests that we have low confidence that the evidence reflects the true effect. Insufficient evidence signifies that the evidence is not available, that we are unable to estimate an effect, or that we have no confidence in the estimate of the effect. We graded the SOE for an outcome only when it was reported in at least one study rated low

or medium risk of bias; studies rated high risk of bias were used to assess the consistency of evidence when they reported the same outcomes in similar populations of workers.

Two reviewers assessed each domain independently and also assigned an overall grade for comparisons for each key outcome; they resolved any conflicts through consensus discussion. If they did not reach consensus, the team brought in a third party to settle the conflict.

Applicability

We assessed the applicability both of individual studies and of the body of evidence. For individual studies, we examined factors that may limit applicability (e.g., characteristics of populations, interventions, comparators, work settings, and geographic settings). Such factors may lessen our ability to generalize the effectiveness of an intervention to use in other occupational groups or work settings. We abstracted key characteristics of applicability into evidence tables. During data synthesis, we assessed the applicability of the body of evidence using the abstracted characteristics.

Peer Review and Public Commentary

Experts in workplace HP and OSH (clinicians and researchers) and experts in evidence-based assessments of workplace and community interventions were invited to provide external peer review of the draft report. AHRQ and an Associate Editor, who are leaders in their respective fields, also provided comments. The draft was posted on the AHRQ Web site for 4 weeks to elicit public comment. We responded to all reviewer comments and noted any resulting revisions to the text in the Disposition of Comments Report. This report will be made available 3 months after AHRQ posts the final review on its Web site.

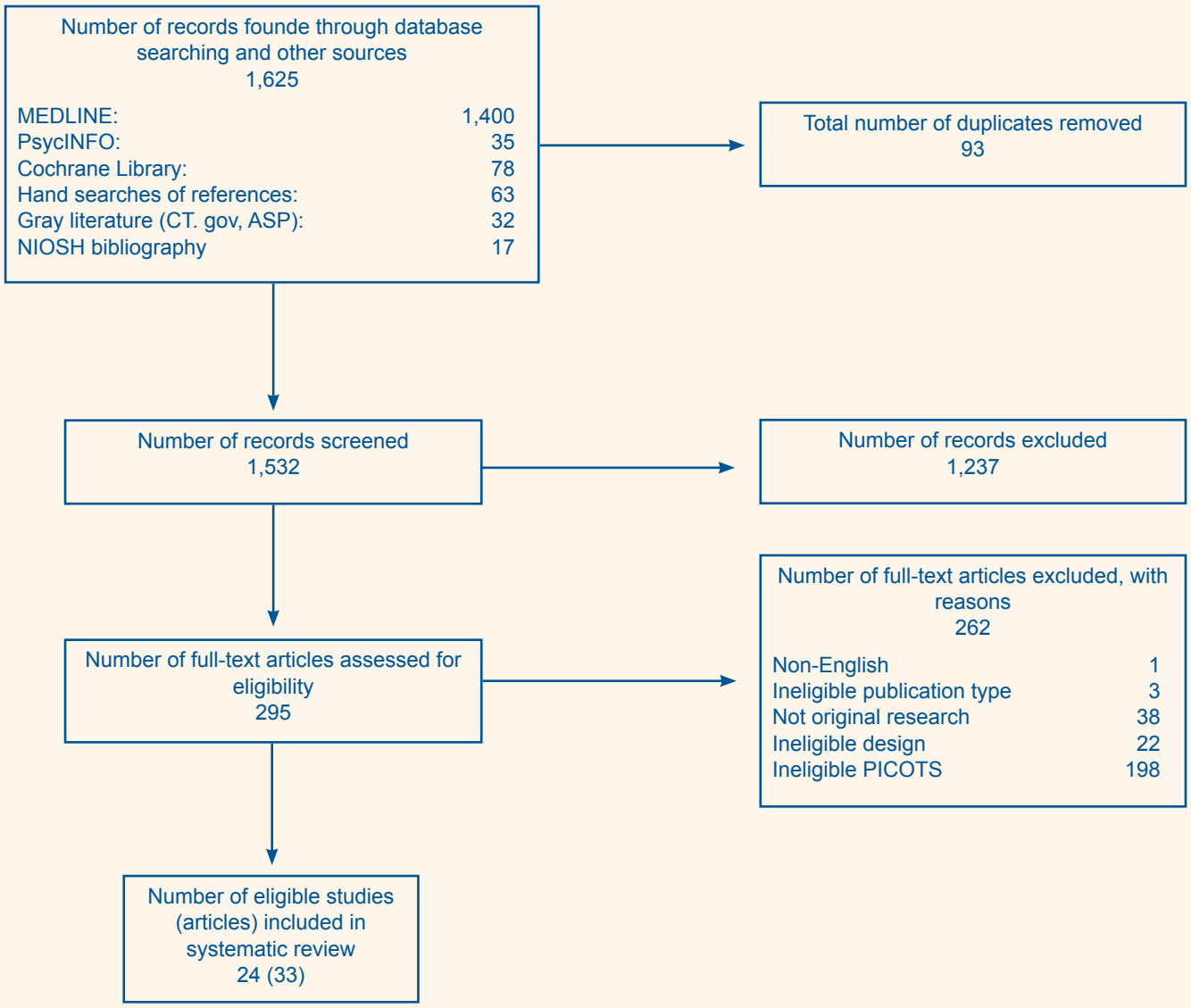
Results

We report results by KQ. For KQ 1 (characteristics of TWH interventions), we describe the characteristics of all included studies using a PICOTS framework. For KQ 2 (treatment effectiveness and harms), we grouped by outcome category. Table A summarizes key findings and SOE grades for KQ 2. The full report contains summary tables for results reported in KQs 1, 2, and 4. In the full report, Appendix C documents risk-of-bias assessments and Appendix D presents SOE grades. Evidence tables (showing all abstracted data by study) will be uploaded to AHRQ's Systematic Review Data Repository for reference and use in future research.[19]

Literature Searches

Figure B (disposition of articles diagram) depicts our literature search results. Searches of all sources identified a total of 1,532 potentially relevant citations. We included 24 studies described in 33 publications.[10,11,20-50] Of the 24 included studies, 15 studies had a concurrent control group and were also eligible for KQ 2. Appendix B provides a complete list of articles excluded at the full-text screening stage, with reasons for exclusion.

Figure B. Disposition of articles for Total Worker Health interventions



ASP = Academic Search Premier; CT.gov = ClinicalTrials.gov; NIOSH = National Institute of Occupational Safety and Health; PICOTS = populations, interventions, comparators, outcomes, timeframes, and settings.

Key Question 1. Characteristics of Studies Evaluating Total Worker Health Interventions

Work Setting and Populations

Across all 24 studies, we encountered substantial heterogeneity with respect to the work settings, populations, and interventions, and the outcomes evaluated. Studies enrolled populations employed primarily in manufacturing, construction, or health care work settings. Workers from the manufacturing industry were more commonly male; workers from the health care and social assistance industry were overwhelmingly female. Commonly targeted workers averaged between 30 and 50 years of age; only one study evaluated a younger workforce (mean <30 years of age) and only one study evaluated an older workforce (mean >50 years of age). Few studies described the baseline health status or medical comorbidity of included populations. Investigators generally did not describe either the OSH or HP

services available at worksites in addition to the intervention under study.

Interventions and Comparators

All studies assessed an intervention focused on an integrated objective (in terms of addressing both occupational hazards and promoting overall health). Eight studies assessed an intervention that involved strategic integration across organizational departments responsible for OSH and HP, and 17 involved worker participation in the development, design, planning, or implementation of the intervention. Six studies assessed an intervention with both strategic integration and worker participation. Most studies were multicomponent interventions; only three evaluated a single-component intervention. Of the 24 included studies, 1 study assessed the effectiveness of integration alone (without added OSH or HP content); 6 studies included mostly HP content (tailored to the specific needs of workers); 5 studies focused primarily on reducing occupational injuries, illnesses, or exposures (including work–life stress and job stress) but also included educational or other content related to promoting healthy behavior; and the remaining 12 studies assessed interventions that included new comprehensive HP and OSH components not previously available to workers. Of the 24 studies, 15 included concurrent control groups, most of which received no intervention. Four studies included active control groups focused on HP or OSH alone.

Outcomes

Overall, these 24 studies assessed a diverse set of outcomes. Few studies measured the same outcomes in similar populations of workers. Approximately half of the studies measured a final health outcome (e.g., quality of life, functional status). Few studies evaluated work-related injuries or illness; work stress and changes in work safety behavior were commonly reported outcomes related to OSH. Commonly reported intermediate health outcomes were body mass index, biomarkers associated with risk of cardiovascular disease (e.g., cholesterol), and health behaviors (primarily physical activity, smoking, and dietary behaviors). Several studies assessed outcomes that we did not include for KQ 2 (i.e., on effectiveness and harms of TWH integrations); the two addressed most often were absenteeism and economic evaluations.

Key Question 2. Effectiveness and Harms of Interventions

Evidence for the effectiveness and harms of TWH interventions for improving outcomes consisted of 12 RCTs, 2 nonrandomized controlled trials, and 1 prospective cohort study.[10,11,20,23,24,26-28,33,36,37,45,46,49,50] Few studies of TWH interventions assessed the same outcomes among similar populations of workers. We rated 5 RCTs as medium risk of bias[27,28,46,49,50] and the other 10 studies as high risk of bias (mainly because of a high risk of selection bias). Most studies had high overall attrition (ranging from 14% to 45%); many studies had differential attrition across study arms. In general, studies rated high risk of bias did not use any statistical methods to address missing data. Other common areas of bias included baseline differences between groups that the investigators did not address in their analyses.

The 15 KQ 2 studies were quite different; few studies of TWH interventions assessed the same outcomes among similar populations of workers. We found no evidence from studies rated medium risk of bias for many important health and safety outcomes of interest. Table A summarizes our key findings by outcomes. We found low SOE to support the effectiveness of TWH interventions for improving rates of smoking and increasing fruit and vegetable intake compared with no intervention; we also found low SOE to support the effectiveness of TWH interventions for reducing sedentary activity at work compared with any comparator. Evidence was insufficient for assessing the effectiveness of integrated interventions for improving quality of life, levels of stress, blood pressure, weight, consumption of red meat, overall physical activity, work-specific physical activity, safety compliance, and safety behaviors; SOE grades for these outcomes are shown in Appendix D.

Table A. Summary of key findings and strength of evidence for Total Worker Health interventions

Population; Intervention, Comparator; Time Point	N Studies; N Subjects Study Limitations	Outcome and Results	Strength of Evidence
Construction laborers[27] and manufacturing workers[20] Integrated intervention vs. no intervention 22–26 weeks	2; 737 Medium or high	**Self-reported 7-day smoking abstinence** One RCT (N = 188 smokers and recent quitters at baseline) rated medium ROB[27] found that more workers in the integrated intervention group than in the control group reported 7-day abstinence at 26 weeks: 19% vs. 8%; p = 0.03.[a] One RCT (N = 490 smokers at baseline) rated high ROB[20] found that more workers at intervention worksites than at control worksites reported 7-day abstinence at 22 weeks (26% vs.17%; p = 0.014).	Low for benefit
Manufacturing workers[10,28] and construction workers[27] Integrated intervention vs. no intervention 26–104 weeks	3; 6,056 Medium or high	**Self-reported fruit and vegetable consumption** Two RCTs rated medium ROB: One RCT (N = 578)[27] found that more workers in the intervention group than in the control group increased consumption of fruits and vegetables: mean increase in servings per day = +1.52 (SD = 3.39) vs. 0.09 (SD = 3.31); p = <0.0001. One RCT (N = 3,092)[28] found that more workers at intervention worksites than at control worksites reported consuming 5 or more servings of fruits and vegetables per day:[b] mean change from baseline = +7.5% vs. +1.1%; p = 0.048. One RCT (N = 2,386) rated high ROB[10] found that more workers at intervention worksites than at control worksites increased consumption of fruits and vegetables: mean change from baseline servings per day = 0.22 vs. 0.09; p = 0.04.	Low for benefit
Sedentary office workers[46,49] Integrated intervention vs. any comparator 16–52 weeks	2; 262 Medium	**Sedentary activity at work** One RCT (N = 412)[46] found decreased sedentary activity in a physical environment intervention group compared with controls: difference between groups in minutes per day spent sedentary = -57.9; 95% CI, 111.7 to 4.2; p = 0.03.[c] One RCT (N = 60)[49] found a decreased percentage of worktime spent sedentary among the integrated intervention group[d] compared with an OSH-only group: -2.0 (95% CI, -4.4 to 0.3) vs. -0.4 (95% CI, -1.1 to 0.2); p = 0.08.	Low for benefit

CI = confidence interval; OSH = occupational safety and health; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation.

[a]This RCT also found benefit for rates of 7-day abstinence of any tobacco use favoring the integrated intervention (19% vs. 8%; p = 0.005).[27]

[b] In the overall sample of workers, there was no difference between intervention and control worksites (mean change from baseline percentage consuming 5 or more servings per day: +5.4% vs. 1.7%; p = 0.41); managers at intervention worksites reported decreased consumption of fruits and vegetables compared with managers at control worksites (mean change from baseline consuming 5 or more servings per day: -5.5% vs. 3.6%; p = 0.048).[28]

[c]There was no difference between the other 2 active comparators (social environment intervention and combined social and physical environment intervention) and the control group on any measure of work-specific physical activity or sedentary behavior outcome.[46]

[d] Workers were randomized to an ergonomic workstation optimization intervention alone or an integrated intervention that included the same ergonomic intervention plus access to a workstation that permitted seated activity.[49]

to primary care services, support from management, availability of resources, and employee stress or strain related to company downsizing during the intervention period.

Key Question 5. Research Gaps

As noted in the Results section, this knowledge base has numerous gaps. Of particular note is the lack of representation across regions of the United States and the appreciable underrepresentation of the service sector (taking into account the prevalence of work-related injuries among workers employed in this sector). Few studies evaluated interventions in populations that varied by race, ethnicity, comorbidity, and other factors. Most studies compared an intervention with both OSH and HP components with no intervention; the effects of the new OSH or HP elements could not be separated from those presumably attributable to integration. Very few or no studies with a concurrent control group examined OSH outcomes, harms, unintended consequences, or any of the following: incidence of injuries or chronic diseases, morbidity associated with chronic diseases, and measures of health services utilization. Many studies had methodological limitations that included differences between intervention and comparison groups at baseline, small sample sizes and power, high overall or differential attrition, and choices of statistical analyses (e.g., no methods to address missing data).

Key Question 6. Future Research Needs

In the Results section, we enumerated numerous areas for future research to fill gaps and for improvements in study designs and methods. These include studying a broader range of workers and worksites in more regions and diverse States of the United States to account for different policies about economic development, labor issues, and worker safety. Moreover, examining similar interventions in other or different groups of workers or work settings might help clarify not only the SOE for interventions but also how generalizable they are across various work settings and populations. Funders should give more consideration to workers in the service sector industries and health care or other parts of the economy with high levels of occupational injuries. Finally, subgroups of workers defined by occupation, age, sex, race, ethnicity, comorbidity, or income, when appropriate, deserve more attention overall and in terms of whether certain categories would benefit more (or less) from TWH interventions.

We emphasized the need for later research to examine directly the effectiveness of integration (in isolation from the effects of any new or improved OSH or HP component) and to describe clearly what programs related to health and safety might already be in place. In terms of outcomes, future studies should do a better job of measuring safety-related outcomes to clarify whether integration improves both OSH and overall health. We noted the need for direct measures of final health outcomes and good selection of intermediate outcomes that link them solidly to final health outcomes, taking the worker population specifically into account. Finally, we advise that future research give more attention to possible negative side effects or unintended consequences of interventions for both organizations and individual workers.

Given that TWH trials may randomize at the worksite level, we call attention to the need to reflect CONSORT principles for reporting and those relating to cluster randomized trials for design and informed consent issues. More well-designed prospective cohort studies or nonrandomized trials with concurrent control groups could inform the SOE related to TWH intervention because studies without a control group are unlikely to yield meaningful information about the effectiveness (or lack of it) of TWH interventions. Finally, we urge investigators to plan ahead for how to handle differences between worker groups at baseline, as well as high attrition and differential attrition, and to use methods to address missing data when necessary, such as imputation of missing data. Studies should address baseline differences between groups when they are present using appropriate statistical methods and report measures of variance (e.g., confidence intervals) for outcome measures.

Findings in Relation to What Is Already Known

This emerging body of literature did not yield any previous systematic review that was similar in scope to ours or that assessed the SOE related to common outcomes of TWH interventions. One prior systematic review[14] and one expert (or narrative) review[13] gave broad overviews of TWH interventions. Our results are, in general, consistent with those in earlier reviews with respect to limitations of the evidence base. For example, although Anger and colleagues noted that integrated interventions improved risk factors for chronic diseases, they concluded that little or no evidence shows that integration itself confers a significant benefit and that this may be "perhaps the most glaring gap in the TWH literature."[14] Like previous reviews, we took a broad approach to defining "integration." Not surprisingly, our review and the two earlier reviews differ slightly in terms of included studies and whether we considered them integrated or not. For example, one study assessing a worksite wellness program designed for firefighters was in the review by Anger and colleagues; we excluded it, however, because it had no explicit coordination between OSH and HP programs and no obvious focus on health protection.[55] Our systematic review methods differ from those of earlier reviews. Prior reviews either did not address potential bias associated with TWH interventions or used study design labels as a proxy for risk of bias of included studies.[14] We used standard techniques for assessing risk of bias for individual trials or observational studies (documented in Appendix C of the full report) and grading the SOE for entire bodies of evidence (Appendix D).

Regarding overall conclusions about the effectiveness of TWH interventions, we assessed the SOE for specific outcomes, whereas prior reviews offered only general statements about the positive effects of TWH interventions or summarized benefits using primarily numbers of statistically significant outcomes across studies; they generally did not consider study limitations, directness, consistency, or precision in evaluating their findings.[13,14] In general, then, the two prior reviews drew stronger conclusions about the benefits of integrated integration than we reached.

Applicability

During our review process, we systematically abstracted key factors (identified a priori) that may affect the applicability of the evidence base (i.e., "the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under real-world conditions"[56]). We focused on issues for populations of workers and worksites in the United States. Studies demonstrating the effectiveness of TWH interventions for improving rates of smoking cessation or increasing the consumption of fruits and vegetables involved U.S. blue-collar workers and used survey data collected before 2004 (and all from the same group of researchers[10,11,27,28]). Since the mid-2000s, workplace HP and OSH programs have very likely improved; whether the results of these trials would be applicable to worksites that already have active HP programs or policies that promote smoking cessation and healthy eating is not clear.

More recent changes in health policy or practice, such as community health interventions and health care, may limit the applicability of studies published 10 or more years ago. After implementation of the Affordable Care Act, national surveys show improvements in self-reported health care coverage and in access to primary care and medications, greater affordability, and better health among younger populations of men, at least in States that expanded Medicaid coverage.[57] Access to smoking cessation services may be more widely available because of these changes; intervention components evaluated in older studies could now be considered "usual care" in some settings.

Limitations of the Review Process

As documented earlier, our inclusion criteria for interventions were broadly defined, and studies meeting those criteria used a range of strategies to

address OSH and especially HP concerns. We based our work on NIOSH definitions for TWH programs and related guidance.[12] Nevertheless, relevant studies were often published before the terms "integrated intervention" or "total worker health" came into use. The definition of TWH itself has shifted in 2015 away from a more narrow focus on integrating OSH and HP to "an approach that advocates for a holistic understanding of the factors that contribute to worker well-being."[7] Our review scope did not include all studies that might fall under the larger umbrella of concerns relevant to TWH.

We did our searches to identify studies that would generally be considered to involve integrated TWH interventions; however, such studies are not indexed by standard or consistent terms. To address this deficiency, we solicited and received a database from NIOSH that listed studies deemed relevant to TWH. Our search strategies had identified the vast majority of these studies. Nevertheless, some studies that we excluded might still be considered related to TWH.

Publication bias and selective reporting of outcomes are potential limitations. Although we searched for unpublished trials and unpublished outcomes, we did not find direct evidence of either of these biases. Many of the included trials were published before trial registries (e.g., ClinicalTrials.gov) became available; had we been able to consult such registries, we would have had greater certainty about the potential for either type of bias.

Finally, for this review, we excluded non–English-language studies, based largely on limitations of time and resources. However, we identified non–English-language studies in our searches and did not see any references that were otherwise likely to meet our inclusion criteria. Searches of the NIOSH references also did not uncover any non–English-language studies. Given this, and the fact that TWH is a relatively new strategy, we believe that limiting our review to English-language studies had little effect on our overall conclusions.

Limitations of the Evidence Base

The limited scope and volume of this evidence base meant that it was inadequate to draw conclusions for some questions or subquestions of interest, even though we went beyond trial data to include observational studies.

For KQ 2, we limited our synthesis to studies with a concurrent control group, but limiting by study design is unlikely to have had a major effect on our SOE grade assessments for effectiveness or harms issues. For KQs 5 and 6, we included pre-post studies, but these questions did not entail making SOE judgments. Furthermore, among studies eligible for KQ 2, many had methodological drawbacks that introduced significant overall study limitations (especially nonresponse to surveys and high overall or differential attrition). It is of particular importance for future research to deal with the following problems: lack of reporting of randomization and allocation concealment, differences in intervention and control groups at baseline, small sample sizes (and thus lack of power for determining intended effects), lack of clarity in defining intervention components, and lack of adequate description or documentation of statistical tests and results.

Conclusions

Overall, we found the body of evidence to be small; heterogeneous in terms of populations, interventions, and measured outcomes; and, in some areas of interest, nonexistent. The small size of the body of evidence is not altogether surprising given that the concept of "integration" is relatively new. The body of evidence may reasonably be expected to grow over the next few years. Evidence of low SOE supported the effectiveness of TWH interventions for improving the following: rates of smoking cessation over 22 to 26 weeks, increasing fruit and vegetable intake over 26 to 104 weeks, and reducing sedentary work activity over 16 to 52 weeks. Evidence was insufficient to assess the effectiveness of integrated interventions for improving the following outcomes: quality of life, stress, blood pressure, weight, overall and work-specific levels of physical activity,

consumption of red meat, safety behaviors, and safety compliance. Effective interventions were informed by worker participation and included comprehensive program content that highlighted the potential additive or synergistic risks of hazardous workplace exposures and health behavior. The applicability of these findings is limited; most trials enrolled blue-collar workers (from manufacturing worksites in Massachusetts or unionized construction workers) before 2004.

Additional adequately powered multisite RCTs or other prospective studies with a concurrent control are needed to replicate encouraging findings, which have been observed to date in only a few trials. Investigators also need to design studies explicitly to assess the benefits of integration separately from new OSH or HP components. Including a broader range of workers in future studies could increase the applicability of TWH interventions and enable reviewers to assess the consistency of findings. It might also answer the question of whether integrated strategies are more effective or less effective in groups of workers who differ by demographic, social, or occupational characteristics that contribute to adverse health outcomes.

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Full Report

This executive summary is part of the following document: Feltner C, Peterson K, Palmieri Weber R, Cluff L, Coker-Schwimmer E, Viswanathan M, Lohr KN. Total Worker Health®. Comparative Effectiveness Review No. 175. (Prepared by the RTI International–University of North Carolina Evidence-based Practice Center under Contract No. 290-2012-00008-I_HHSA 29032009T.) AHRQ Publication No. 16-EHC016-EF. Rockville, MD: Agency for Healthcare Research and Quality; April 2016. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

AHRQ Pub. No. 16-EHC016-1-EF
April 2016