



Effective Health Care Program

Total Worker Health® Executive Summary

Background

The American worksite has been a venue for both health protection and health promotion programs. Health protection programs are interventions aimed specifically at preventing occupational injuries or illnesses. Work-related injuries and illnesses lead to morbidity, mortality, and considerable financial and social costs.¹⁻³ Health promotion (HP) programs, often called wellness programs, are interventions aimed at improving overall health and well-being. They often address modifiable behavior risk factors such as smoking, physical activity, and diet, which are leading causes of morbidity and mortality in the United States.⁴

Traditionally, occupational safety and health (OSH) programs and HP programs have functioned independently within the workplace.⁵ Recently, interest in integrating these programs has grown appreciably;^{5,6} this interest grows out of evidence supporting the idea that workplace factors contribute to adverse health outcomes traditionally considered to be unrelated to work (e.g., cardiovascular disease and depression).⁷ The National

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Institute for Occupational Safety and Health (NIOSH) focused attention on integrated approaches in 2011 by creating the Total Worker Health® (TWH) program. NIOSH summarized the rationale for integrating OSH and

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HP programs in 2012 as follows:⁸ (1) risk of adverse health outcomes is increased by exposures to both occupational hazards and behavioral risk factors; (2) occupational exposures and risk factors for chronic diseases are related and may have synergistic adverse health effects; (3) workers at highest risk for hazardous occupational exposures often have more risk factors for chronic disease; and (4) integrating OSH with HP efforts may increase worker participation in health-related programs and benefit the broader work environment.

TWH is currently defined as “policies, programs, and practices that integrate protection from work-related safety and health hazards with promotion of injury and illness prevention efforts to advance worker well-being.”⁹ Earlier descriptions of TWH focused primarily on the integration of OSH and traditional worksite HP programs;⁸ NIOSH now emphasizes recognition that work is a social determinant of health and that job-related factors (e.g., wages, hours of work, workload, and stress levels) are important factors in determining the well-being of workers.⁹

TWH is a trademarked term that was not commonly used in past studies of integrated interventions. For this review, we use the term “TWH interventions” to refer to integrated interventions that are consistent with NIOSH’s TWH initiative. A range of interventions that differ in content, complexity, and approach to integration could be considered consistent with NIOSH’s TWH initiative. For example, prior studies considered to fall under the TWH umbrella were developed through strategic intraorganizational coordination and employee participation that pair organizational change with individual-level content focused simultaneously on occupational hazard(s) and HP.^{10,11} TWH interventions can also consist of a subset of these traits; for example, an intervention may combine components aimed at improving ergonomics and promoting physical activity with the aim of decreasing musculoskeletal injuries and improving overall health. Prior research has outlined indicators and metrics of “integration” important in TWH interventions that include factors such as organizational leadership; data integration;

organizational coordination across departments responsible for health protection and HP; adequate resources; accountability; and training.¹² However, no research has evaluated these indicators separately in order to isolate whether (and to what extent) they contribute to intervention effectiveness beyond other factors such as intervention content.

Rationale for Evidence Review

The goal of this review is to identify gaps in the evidence about TWH effectiveness to help identify future research priorities. This executive summary is based on the methods, data, conclusions, and appendixes presented in the full report.

Previous reviews of the literature have differed in scope (i.e., used different search and inclusion criteria and addressed a narrower set of Key Questions [KQs]), thereby including studies of varied rigor and scope.^{13,14} Moreover, the effectiveness of the interventions in individual studies and in the prior reviews has been judged based on various metrics (e.g., various improvements in health behaviors, physiologic outcomes, and economic outcomes, or a count of the number of significant outcomes). As a result, uncertainty remains about the benefit of TWH interventions for improving specific health and safety outcomes. These factors underscore the need for the current systematic review to synthesize the literature supporting TWH interventions, assess the strength of evidence (SOE) for important outcomes, and highlight research gaps and future research needs.

Scope and Key Questions

The purpose of this review is to provide an evidence report that the National Institutes of Health (NIH), Office of Disease Prevention, Pathways to Prevention (P2P) Workshop Program can use to inform a workshop focused on TWH.¹⁵ This review will describe the body of evidence evaluating TWH interventions, assess the effectiveness of TWH interventions for improving health and safety outcomes, highlight the research gaps, and call out future research needs. The P2P Workshop Program

Panel will use the evidence report as a resource to develop a summary of the current state of the science and future research needs related to TWH interventions. Specifically, we address the following six KQs.

Key Question 1. What populations, work settings, intervention types, and outcomes have been included in studies assessing integrated interventions?

Key Question 2. What is the effectiveness of integrated interventions for improving the following outcomes, and what are the potential harms?

- a. Health and safety outcomes (e.g., cardiovascular events or incidence of work-related injuries)
- b. Intermediate outcomes (e.g., change in blood pressure, tobacco use, or hazardous exposures)
- c. Utilization outcomes and occupational injury and illness surveillance outcomes (e.g., hospitalizations or measures of workers' compensation claims)
- d. Harms (e.g., discrimination or victim blaming)

Key Question 3. What are the characteristics of effective integrated interventions?

Key Question 4. What contextual factors have been identified as potential modifiers of effectiveness in studies of integrated interventions?

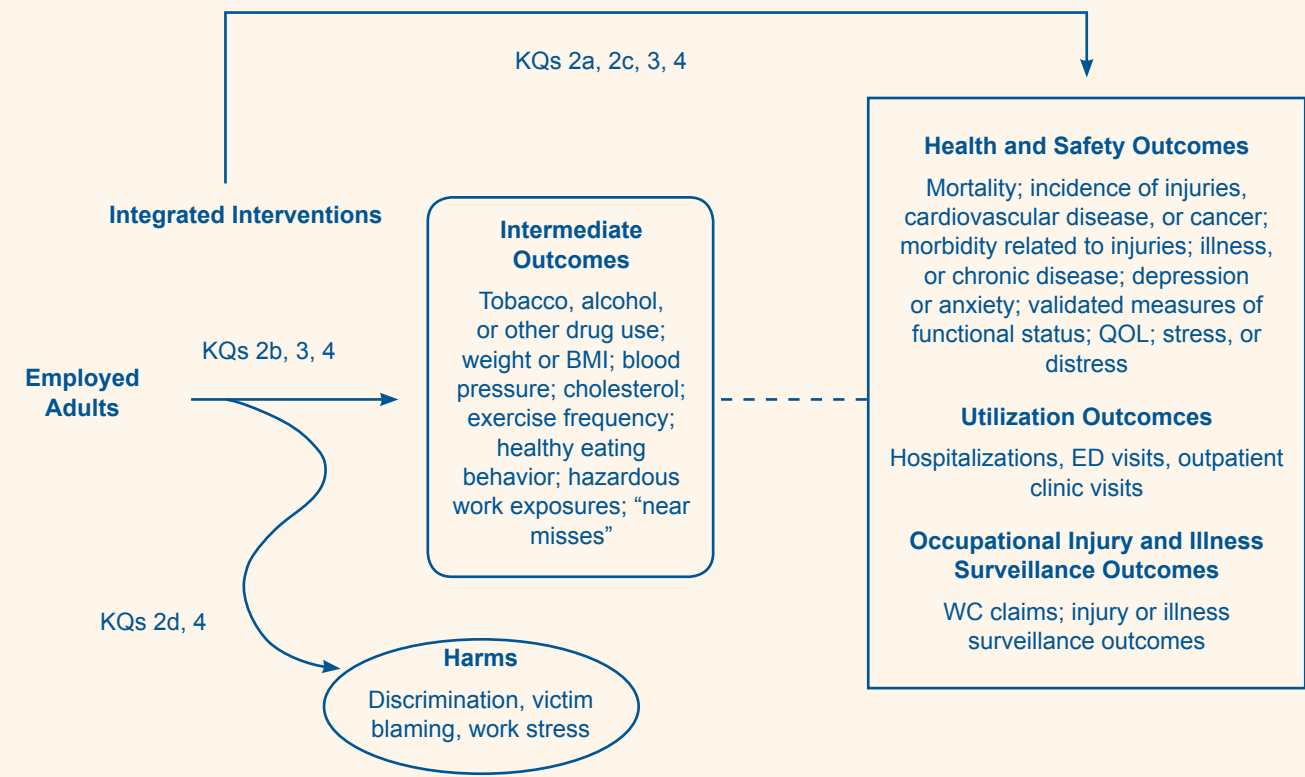
Key Question 5. What evidence gaps exist in the body of literature assessing the effectiveness of integrated interventions in terms of the following: populations, work settings, intervention types, outcomes, study designs, research methods, and contextual factors that may modify intervention effectiveness?

Key Question 6. What are the future research needs?

Analytic Framework

We developed an analytic framework to guide the systematic review process (Figure A). The analytic framework illustrates the population, interventions, outcomes, and adverse effects that guided the literature search and synthesis.

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

this bibliography to ensure that our database searches had not missed relevant citations. We searched reference lists of pertinent review articles for studies that we should consider for inclusion in this review.

Inclusion and Exclusion Criteria

We developed inclusion and exclusion criteria with the PICOTS framework (populations, interventions, comparators, outcomes, timeframes, and settings) in mind. We considered only trials or studies published in English.

The population of interest is employed adults. We excluded studies that enrolled only children or adolescents younger than 18 years of age.

Interventions of interest included any “integrated” intervention that met the definition of a TWH strategy (as defined earlier¹²). To meet inclusion criteria, an intervention had to have a component aimed specifically at improving workplace health and safety and a component aimed at improving overall health, health behaviors, or risk factors for chronic diseases. We did not create inclusion or exclusion based on the degree or type of integration.

Included studies for KQ 2 (effectiveness and harms of TWH interventions) had to have a concurrent control group. Acceptable comparisons included (1) a different integrated intervention that differed in content, complexity, or other factors; (2) an OSH intervention or HP intervention only (i.e., any active comparator that was not integrated); and (3) no intervention or usual work practice. For descriptive purposes relating to KQs 1, 4, 5, and 6, we included studies assessing an eligible intervention in only one group (i.e., pre-post studies).

We specified a broad range of outcomes—intermediate and final health benefit outcomes and treatment harms (Figure A). We did not exclude studies based on the outcomes reported. For KQ 2, we limited our evidence synthesis to commonly reported outcomes that are considered to be important measures of worker health and safety. We determined which outcomes are common and considered important in this body of literature by reviewing prior studies of TWH interventions and asking for

input from Technical Expert Panel members on our inclusion and exclusion criteria prior to finalizing the research protocol. Final health outcomes, for example, included quality of life, functional status, and occupational illnesses and injuries. Intermediate outcomes included rates of smoking cessation, healthy eating behavior, and outcomes related to hazardous workplace exposures or “near misses.” We also included health care utilization outcomes, rates of workers’ compensation claims, and short-term disability claims. Finally, we searched for harms associated with TWH interventions, such as increased barriers to reporting work-related injuries or illnesses, work stress, discrimination, and victim blaming.

We included studies conducted in any workplace setting in a developed country (“very high” Human Development Index according to the United Nations Development Programme).¹⁶

Study designs included randomized controlled trials (RCTs), nonrandomized controlled trials, prospective cohort studies, and pre-post studies. We did not include prior reviews but captured these in our database searches and used them to identify studies that our searches may have missed.

Study Selection

Trained members of the research team reviewed article abstracts and full-text articles. Two members independently reviewed each title and abstract using the predefined inclusion and exclusion criteria. Studies marked for possible inclusion by either reviewer underwent a full-text review. Two members of the team independently reviewed each full-text article. If both reviewers agreed that a study did not meet the eligibility criteria, we excluded it; each reviewer recorded the primary reason for exclusion. If reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a third member of the review team.

We screened unpublished studies and reviewed scientific information packages using the same title/abstract and full-text review processes. The project coordinator tracked abstract and full-text reviews in an EndNote database (EndNote® X4).

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.

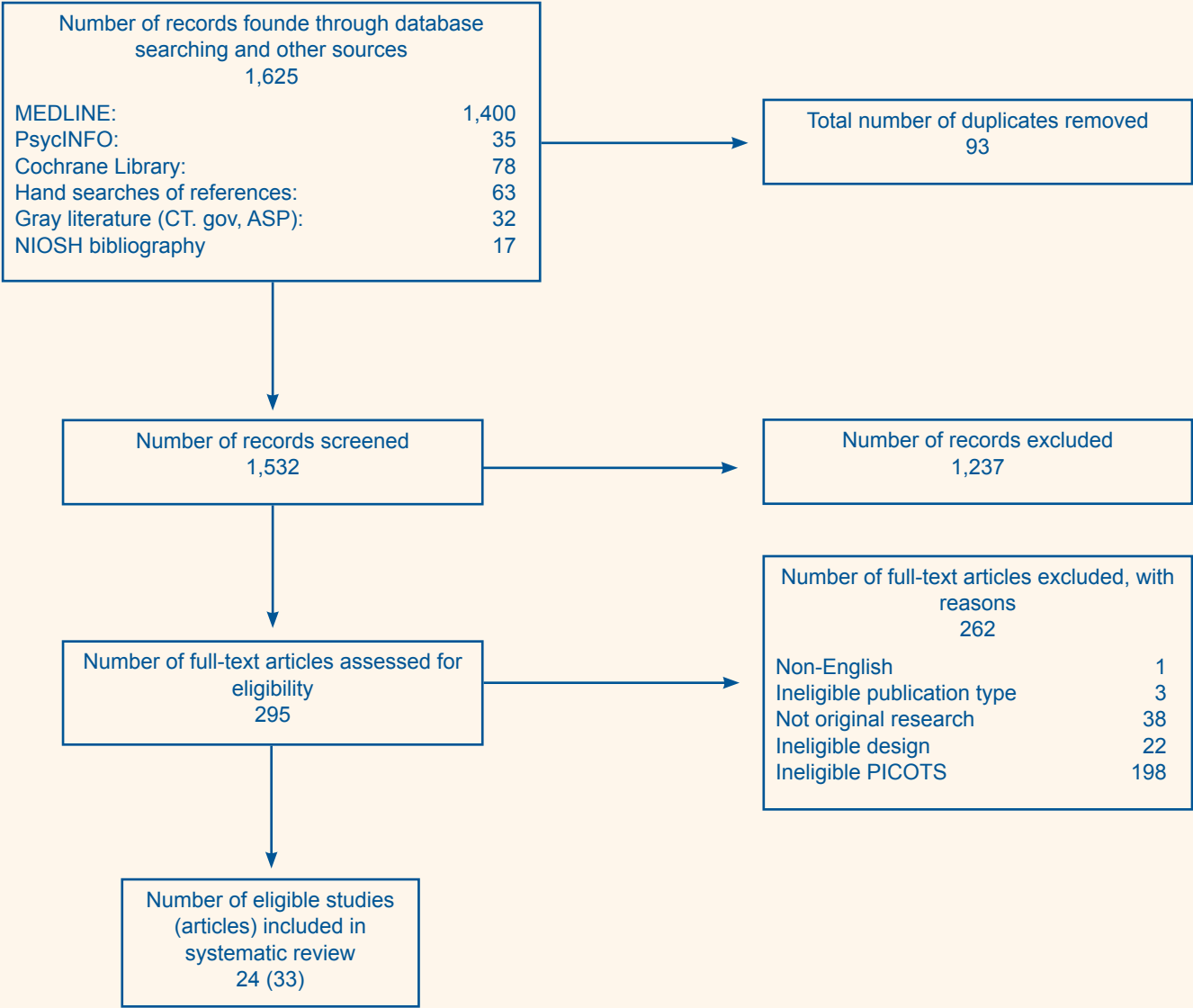
Results

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.

^aThis 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

^bIn 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

^cThere 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

^dWorkers 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

Key Question 3. Components of Effective Interventions

We evaluated common characteristics of interventions that were effective for improving any outcome eligible for KQ 2 for which the SOE for benefit was at least low. We focused on characteristics of interventions that relate to the approach to integration and specific content of the intervention. Overall, we were able to make very few SOE conclusions because of the limitations of the evidence base; effective interventions were heterogeneous, and separating individual components from the overall types (or “bundles”) of interventions that showed efficacy for outcomes eligible for KQ 2 was not possible. Most effective interventions were informed by worker participation in the development, design, planning, or implementation of the intervention, or in more than one of these steps. Most effective interventions tailored intervention components or materials to cultural or social aspects of the worker population (e.g., to workers with low literacy skills or workers for whom English is not the first language). All effective interventions were multicomponent complex interventions that reinforced messages about health and safety through multiple levels of influence or multiple modes of delivery (or both) over time.

Key Question 4. Contextual Factors

We abstracted data from included studies that related to contextual factors that the original authors had identified as potential modifiers of intervention effectiveness. We included factors that had been noted in the results (e.g., whether the intervention was more or less effective at worksites that differed by a specific contextual factor) and also those mentioned in the discussion that could have potentially modified the effectiveness of interventions.

Eight studies identified a contextual factor that could have played a role in modifying the effectiveness of interventions. Work organization factors and union membership status were the two most commonly mentioned contextual factors. Other factors mentioned in at least one study included the following: presence of another (concurrent) OSH or HP policy implemented during the study

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

Key Question 5. Research Gaps

We found numerous gaps in the literature base supporting TWH interventions in terms of work settings and populations, interventions, comparators, and deficiencies in methods.

Work Settings and Populations

No study enrolled workers from States in the Southwest; only one study each was conducted in a Southeastern or Western State (Arkansas and Oregon, respectively). Only one U.S. study enrolled a population across different U.S. regions.²⁷

No studies enrolled workers from industries in these sectors: wholesale and retail trade; information (publishing, broadcasting, telecommunications); real estate; professional, scientific, and technical services; educational services; arts, entertainment, and recreation; or accommodation and food services. The service sector as a whole (e.g., retail, transportation, communications industries, health care) is underrepresented in included studies when considering the prevalence of work-related injuries among workers employed in this sector. In terms of specific occupational groups, few studies enrolled office and administrative support workers (the occupational group with the largest employment in the United States).⁵¹ The following occupations were not represented in included studies: sales and related occupations (the second largest major occupational group in the United States)⁵¹ and food preparation and serving workers (the third largest major occupational group in the United States).⁵¹

No study enrolled populations of workers who were very young or very old. No study addressed differences in outcomes among subgroups of workers defined by age, sex, race, ethnicity, comorbidity, or income. People who work part time (regardless of their occupation) were often excluded from studies.

Interventions

Studies evaluated quite diverse interventions; the type and level of integration involved in interventions varied substantially. We found no direct evidence on whether certain strategies of integration are more or less effective than others. A minority of included studies (8 studies) evaluated an intervention that included organizational integration (e.g., multiple departments within the work setting involved with planning, implementing, and managing the intervention).

We found no studies that directly assessed whether specific combinations or specific types of program content were more or less effective than other combinations. Studies differed in terms of the degree to which program content focused on OSH concerns versus HP concerns.

We could not assess whether strategies were more or less effective based on their complexity (single vs. multiple components) or level of influence (environmental or administrative controls, individual worker education, or both). Most studies assessed complex heterogeneous interventions that targeted both the worker and the worksite. Few studies assessed single-component interventions aimed at improving the work environment or work structure with the associated goals of improving OSH and promoting personal health.

Comparators

In general, studies were not designed to assess directly the effectiveness of integration alone (compared with no integration). Most studies compared an intervention that addressed both OSH and HP with no intervention. The effects of the new HP or OSH component (or both) offered to the intervention group could not be separated from the effects of integration. Studies that compared an intervention with no intervention or usual workplace programs generally did not describe the OSH or HP programs already in place and available to workers.

Outcomes

Although we considered a wide range of outcomes for this review, we were able to rate the evidence for only three: smoking cessation, changes in fruit and vegetable consumption, and changes in sedentary work activity. Very few studies measured outcomes important to OSH. Whether integrated interventions improve workplace safety (compared with OSH programs or policies that are not integrated with HP) is unclear.

No study eligible for KQ 2 reported on the following outcomes: incidence of injuries, cardiovascular disease, or cancer; morbidity related to injuries, illnesses, or chronic disease (including work-related injuries and illnesses); depression or anxiety; body mass index; or use of health care. A few studies (all high risk of bias) reported on the following: validated measures of quality of life or functional status, stress (job or general stress), rates of workers' compensation claims, short-term disability claims, alcohol use, and illicit drug use.

None of these studies prespecified harms as an outcome of interest. We found no information pertaining to increased barriers to reporting work-related injuries or illnesses, work stress, adverse effects on personal health, discrimination, or victim blaming.

Deficiencies in Methods

As already noted, nine studies used a pre-post design; because of the inherent risk of bias in pre-post studies, we did not include them in our assessment of the benefits and harms of TWH interventions. The 15 studies eligible for KQ 2 still had numerous methodological limitations. The RCTs often did not report on randomization and allocation concealment adequately. Most RCTs randomized worksites (not workers), but the numbers of worksites randomized were sometimes small. Investigators often did not adequately describe the flow of participants (especially for studies that randomized or assigned interventions at the worksite level).

Most studies mounted surveys before and after an intervention, but response rates to baseline surveys among eligible workers were sometimes low or not reported. This factor contributed to selection bias. Overall attrition was high in several studies; most studies performed a complete-case analysis; participants (or worksites) with missing data were excluded from the analysis. We encountered baseline differences between groups in several studies; statistical analyses often did not address these differences. Several studies had small sample sizes and thus lacked power for determining intended effects.

Investigators sometimes did not provide information on their statistical methods; also, authors sometimes did not provide measures of variance (e.g., confidence intervals) for outcomes. In several studies, contamination of the control arms compromised internal validity; for example, another worksite policy or program initiated during the intervention period could have influenced outcomes measured in the study.

Finally, in some cases, the length of followup may not have been adequate to assess the stability of findings over time. Only seven studies measured outcomes at or beyond 1 year.

Key Question 6. Future Research Needs

Work Settings and Populations

Future research could target specific worksites in diverse regions of the United States that differ in terms of State government policy on economic development and labor; these factors can influence where employers locate and the attention they give to worker safety.

The applicability of interventions that were effective for reducing smoking, improving fruit and vegetable consumption, and reducing sedentary work activity is limited. Future studies should consider similar interventions in other groups of workers (e.g., other blue-collar workers) to help clarify (1) the SOE for

these interventions and (2) the applicability across various work settings and populations.

Consideration should be given to a broader set of populations of workers in the service sector—such as retail, transportation, and communications industries and health care—in future TWH interventions. These populations have a high burden of occupational injuries. Occupational groups representing the largest number of U.S. workers should also be a focus of future research; these include (but might not be limited to) office and administrative support workers, sales and related occupations, and food preparation and serving workers. Future studies could enroll workers from diverse work settings (who receive a similar intervention, for example) to assess which factors related to the work setting modify the benefits (and potential harms) of TWH interventions. This approach might include recruiting worksites that differ by size, ownership of the enterprise (e.g., whether private or public sector), work organization (e.g., full- vs. part-time job patterns), and unionization.

Future studies could assess whether outcomes differ among subgroups of workers defined by occupation, age, sex, race, ethnicity, comorbidity, or income (when appropriate). Whether certain categories of workers would benefit more than others from TWH is not clear. Future studies could enroll populations who are likely to have specific concerns related to work–life balance (e.g., caregivers of young children or elderly parents, single parents) or workers with unique health and safety concerns (older workers or those with disabilities).

Interventions

Future studies should clearly describe the approach used to integrate OSH and HP programs, policies, or goals. Investigators should lay out a framework for how the integrated intervention addressed both OSH and overall health. Studies should focus on interventions targeted at work environment or work structure. Work schedules (e.g., shift work, work hours), for example, have been highlighted as an

issue relevant to TWH. Few studies have assessed whether specific integrated strategies that modify the work environment improve worker health more than those focusing primarily on providing education or behavioral counseling to individual workers.

Comparators

An established body of literature supports the efficacy of worksite wellness interventions on smoking and other important outcomes.⁵² Future studies should try to assess directly the effectiveness of integration itself; in other words, this aspect of TWH interventions should be isolated from the effects of a new or improved OSH or HP component. Studies should directly compare an integrated approach with a program that has similar OSH and HP elements available but does not deliberately coordinate them. In addition, investigators should clearly describe what programs related to health and safety are already in place and available to workers outside the intervention being evaluated.

Outcomes

Future studies should consider the feasibility of measuring OSH outcomes. To understand whether integration improves both OSH and HP, researchers need to examine indicators of improved safety.

Future studies should also consider direct measures of worker health if possible. For example, investigators should try to use validated measures of health status, functional status, and wellness. Researchers should measure the incidence or morbidity associated with chronic diseases when feasible, particularly in populations of workers at higher risk of chronic conditions (e.g., older workers).

Research teams should also choose intermediate outcomes carefully. These outcomes should be based on strong evidence for linkages to final health outcomes and for relevance to a particular population of workers.

Finally, future studies should consider assessing harms or potential unintended consequences of the interventions. Measures of harms and unanticipated

effects should be made at both the individual worker and organizational levels.

Deficiencies in Methods

Worksite randomized trials should follow the recommendations for reporting outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement extension to cluster randomized trials⁵³ or the Ottawa Statement on the ethical design and conduct of cluster randomized trials.⁵⁴ In particular, authors should provide a clear diagram to show the flow of participants from group assignments through the final analysis. Of the 24 studies we included in this review, 9 had a pre-post design; because of the inherent risk of bias in pre-post studies, we did not include them in our assessment of the benefits and harms of TWH interventions. Among the 15 studies eligible for KQ 2 (i.e., those with a concurrent control group), many had methodological limitations.

Randomized trials are not always feasible because of barriers associated with studying populations of workers. Well-designed prospective cohort studies (or nonrandomized trials) with a concurrent control group could inform the SOE related to TWH interventions. Studies without a control group are unlikely to contribute significantly to an understanding of the SOE supporting TWH interventions because of the inherent bias in the design; these designs should be avoided.

Investigators should plan for high attrition, and differential attrition between intervention and control groups. In addition, they should use methods to address missing data (e.g., imputation of missing data) when attrition is high; these methods should be informed by the potential reasons for missing data and whether the outcomes of participants are likely to change after they drop out.

Studies should address baseline differences between groups (when they are present) using appropriate statistical methods. Furthermore, investigators should report measures of variance (e.g., confidence intervals) for all outcomes they evaluate. Finally, in reporting their studies, authors should highlight

whether other concurrent policies or programs related to health and safety had been in place or implemented during the intervention in question; this will enable them to assess bias associated with contamination.

Discussion

Key Findings and Strength of Evidence

We limit our discussion to key findings from the 24 included studies for all KQs. Other results can be found in the Results section and in more detail in the full report.

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

Work settings, populations, interventions, and outcomes all differed considerably across this evidence base. Studies enrolled populations employed primarily in manufacturing, construction, or health care settings. Overall, targeted workers were mainly 30 to 50 years of age. All studies assessed an intervention focused on an integrated objective to address both OSH and HP; 8 interventions included strategic organizational integration across departments; 17 included worker participation in the development, design, planning, or implementation of the intervention; and 6 included both strategic coordination and worker participation. Most studies were multicomponent and included HP and OSH components not previously available to workers. The outcomes assessed were highly varied and usually not measured in similar populations of workers.

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} Of these, 5 RCTs were medium risk of bias^{27,28,46,49,50} and the others high risk of bias. Studies rated medium

risk of bias (rather than high) provided little or no evidence for many important health and safety outcomes of interest. Some evidence (low SOE) supported the effectiveness of TWH interventions for improving rates of smoking cessation, increasing fruit and vegetable intake, and decreasing sedentary work activity. Evidence was insufficient to permit us to assess the effectiveness of integrated interventions for improving quality of life; decreasing stress, blood pressure, weight, or consumption of red meat; or increasing safety compliance and safety behaviors.

Key Question 3. Components of Effective Interventions

We evaluated common characteristics of interventions that were effective for improving any outcome eligible for KQ 2 for which the SOE for benefit was at least low. Four studies, primarily enrolling blue-collar manufacturing and construction workers, contributed to our SOE grades for smoking cessation and healthy eating outcomes, and two studies enrolling office workers contributed to our SOE grade for sedentary work activity. Most effective interventions were informed by worker participation in the development, design, planning, or implementation of the intervention, or in more than one of these steps. All effective interventions included comprehensive program content that highlighted the potential additive or synergistic risks of hazardous workplace exposures and health behavior. Most interventions tailored intervention components or materials to cultural or social aspects of the worker population.

Key Question 4. Contextual Factors

We abstracted data from included studies that related to contextual factors identified by authors as potential modifiers of intervention effectiveness. Of the 24 included studies, 8 identified a contextual factor that could have influenced the effectiveness of interventions, mainly work organization factors and union membership status. Other factors from at least one study included the following: presence of another concurrent OSH or HP policy implemented during the study period, health insurance status or access

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 review¹⁴ and one expert (or narrative) review¹³ 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

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