

Evidence-based Practice Center Systematic Review Protocol

Project Title: Total Worker Health

I. Background and Objectives for the Systematic Review

Workplace injuries and illnesses are common. They lead to mortality, morbidity, and considerable financial and social costs.¹⁻³ At the same time, modifiable risk factors for chronic diseases such as smoking, physical inactivity, and poor diet are leading causes of morbidity and mortality in the United States.⁴ The Community Preventive Services Task Force recommends worksite interventions (assessments of health risks with feedback combined with health education programs) on the basis of strong evidence of effectiveness in improving one or more health behaviors or conditions in populations of workers (e.g., reduced tobacco use and fewer lost work days because of illness or disability).⁵

Traditionally, health protection programs (interventions aimed specifically at preventing occupational injuries or illness) and health promotion programs (interventions aimed at improving personal health) have functioned independently within the workplace.⁶ Interest in integrating these programs has grown appreciably in the past decade. The following are examples of organizations who have promoted integrated approaches to improving worker health: National Institute for Occupational Safety and Health (NIOSH),⁷ the American College of Occupational and Environmental Medicine,⁶ the International Association for Worksite Health Promotion,⁸ and the World Health Organization.⁹

NIOSH has focused attention on integrated approaches to worker health by creating the Total Worker Health™ (TWH) program. TWH is defined as a “strategy integrating occupational safety and health protection with health promotion to prevent worker injury and illness and to advance worker health and well-being.”¹⁰ The TWH program supports research and promotes “best practices” of integrative approaches that address health risk arising from both the work environment (physical and organizational) and individual behaviors.⁷ TWH is a trademarked term, and it is not a term that has been commonly used in past studies of integrated interventions. For the purposes of this review, we will use the term “TWH interventions” to refer to integrative interventions that are consistent with NIOSH’s TWH initiative.

TWH interventions are often multicomponent, complex interventions. Interventions often pair organizational changes or policies with individualized content focused on a specific occupational hazard and one or more health behaviors or risk factors for chronic disease. TWH interventions include, for example, strategies aimed to both increase physical activity and prevent musculoskeletal work-related injury.^{11,12} Other TWH interventions have integrated work site-based health promotion into on-site safety training programs; for example, smoking cessation interventions paired with education and other programming that also addressed the synergistic effect of tobacco and work-related chemical or dust exposure.¹³ Similarly, an integrated worksite cancer prevention program

incorporated reducing exposure to hazardous substances and individual interventions focused on nutrition and tobacco use.¹⁴ Other interventions have addressed worker safety and mental health through work redesign.¹⁵ For example, an intervention in a Dutch manufacturing plant incorporated physical exercise, health education, and eventually modification of work organization and environment to reduce stress and increase job control.¹⁶

Despite a growing interest in TWH interventions, they pose considerable challenges. First, access to integrative interventions for certain occupational groups may be limited. For example, low-income workers in physically demanding jobs (who are often at higher risk of occupational injuries and illnesses than higher-income workers) and employees of smaller companies may have less access to TWH interventions than other workers. Small employers, which often do not offer health insurance, may struggle to provide comprehensive TWH interventions. Private health insurance carriers currently provide the majority of funding for worksite health promotion services.¹⁷ A recent narrative review noted that most studies evaluating TWH interventions involve large employers.¹⁸

Second, published studies evaluating TWH interventions vary widely in their rigor and scope. Effectiveness of these interventions has been judged based on various metrics (e.g., improvement in health behaviors, physiologic outcomes, and economic outcomes). Whether certain approaches to integration (or specific program content) are more or less effective than other approaches in promoting worker health remains unclear. Most interventions have enrolled very specific occupational groups; the results of these studies may not be applicable to populations in a different physical or organizational work environment.

Third, many contextual factors affect worker health; these include, for instance, health care coverage, availability of paid sick leave, and work culture. These factors have not been widely considered as a modifier of intervention effectiveness.

The body of evidence evaluating integrative interventions has grown in recent years. The purpose of this review is to provide an evidence report that the National Institutes of Health, Office of Disease Prevention, Pathways to Prevention Workshop Program can use to inform a workshop focused on TWH.¹⁹ This review will describe the body of evidence evaluating TWH interventions, evaluate the effectiveness of TWH interventions for improving health and safety outcomes, highlight the research gaps, and inform future research needs. The Pathways to Prevention 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.

II. The Key Questions

1. What populations, work settings, intervention types, and outcomes have been included in studies assessing integrated interventions?
2. What is the effectiveness of integrated interventions for improving the following outcomes:
 - 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 worker's compensation claims)
 - d. Harms (e.g., discrimination or victim blaming)
3. What are the characteristics of effective integrated interventions?
 4. What contextual factors have been identified as potential modifiers of effectiveness in studies of integrated interventions?
 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?
 6. What are the future research needs?

For the above KQs, the following PICOTs criteria apply:

- **Population(s):**
 - Employed adults (18 years of age or older)
- **Interventions:**
 - Any “integrated intervention” that meets the definition of a TWH strategy, defined as “a strategic and operational coordination of policies, programs, and practices designed to simultaneously prevent work-related injuries and illnesses, and enhance overall workforce health and well-being.”²⁰ Interventions may include a range of approaches that focus on changes in policy, organizational structure, work organization (e.g., removing working conditions that serve as obstacles to healthy behavior) or environmental factors. Integrated interventions may also provide individual education, counseling, training, or social support (or combinations of these components) aimed at both occupational health and safety and health promotion.
 - To meet inclusion criteria for this review, an integrated intervention must include 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 will not judge inclusion and exclusion based on the degree of “integration” (or type of integration) between health protection and health promotion programs. Variations in the degree to which interventions are “integrated” and how integration is accomplished, as well as the specific intervention components included, are considered characteristics of the integrated interventions and are the focus of KQ 1 (characteristics of interventions) and KQ 3 (characteristics of effective interventions).

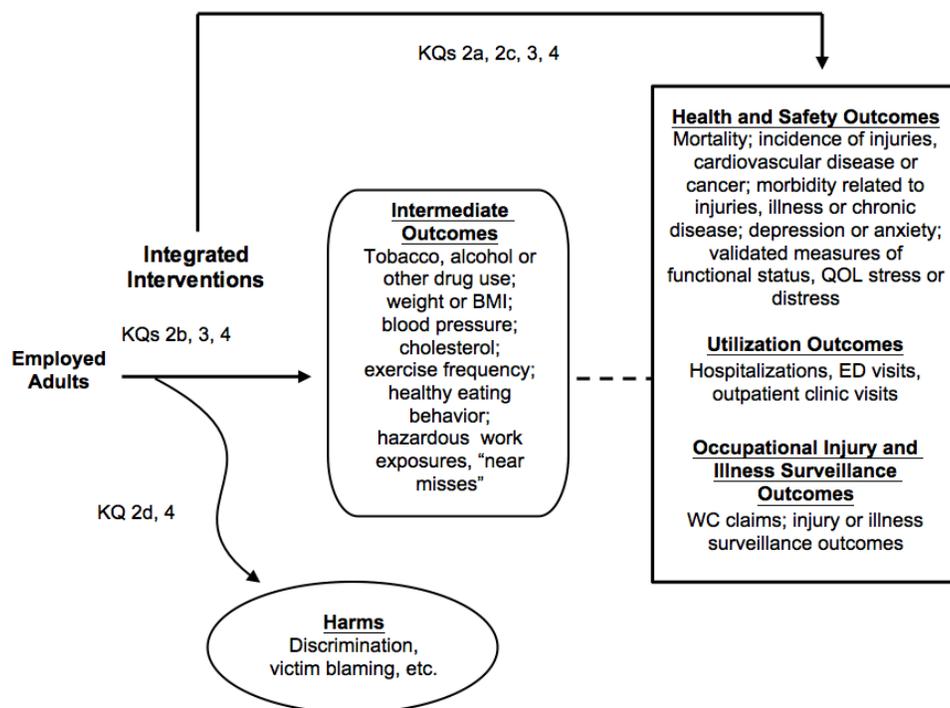
- **Comparators:**
 - **All KQs:** Usual practice, usual care, standard care, or no intervention; head-to-head studies comparing two different TWH interventions
 - **KQ 1 only:** “Pre-post” comparisons (in addition to the comparators listed above)
- **Outcomes for each question:**
 - **KQ 1:** This is a descriptive summary of studies that meet inclusion criteria for all other domains (e.g., intervention and study design criteria); we will describe the range of outcomes reported across trials (in addition to the ones listed below for KQs 2, 3, and 4).
 - **KQ 2a: Health and safety outcomes:** Mortality; incidence of injuries, cardiovascular disease or cancer; morbidity related to injuries, illnesses or chronic disease (including work-related injuries and illnesses); depression or anxiety; validated measures of functional status, quality of life, stress or distress
 - **KQ 2b: Intermediate outcomes:** Tobacco, alcohol or other drug use; weight or body mass index (BMI); blood pressure; cholesterol; incidence of diabetes; frequency of physical activity; healthy eating behavior (e.g., increased consumption of fruit and vegetables); rates of hazardous exposures or “near misses”
 - **KQ 2c: Utilization outcomes and Occupational Injury and Illness surveillance outcomes:** Hospitalizations, emergency department visits, or outpatient clinic visits; measures of worker’s compensation claims or injury or illness surveillance outcomes
 - **KQ 2d: Harms:** Increased barriers to reporting work-related injuries or illnesses, work stress, adverse effects on personal health, discrimination, victim-blaming
 - **KQ 3:** This is a descriptive summary of interventions that are effective for improving a health and safety outcome or an intermediate outcome (from our KQ 2 analysis).
 - **KQ 4:** This is a descriptive summary of contextual factors identified as potential modifiers of intervention effectiveness across all included studies. Contextual factors may include (but are not limited to) the following: legal-regulatory environment (e.g., state laws with respect to union representation); employer characteristics, policies, or benefits (e.g., availability of health insurance coverage or paid sick leave); work organization (e.g., shift work); and social or economic factors (e.g., income or availability of community resources to support or promote health).
 - **KQs 5, 6:** These entail a descriptive summary of the research gaps and future research needs related to TWH interventions (respectively).

- **Timing:**
 - **All KQs:** Any duration of followup
- **Settings:**
 - **All KQs:** Any work setting; studies conducted in a developed country (“very high” human development index per the United Nations Development Programme).

III. Analytic Framework

The analytic framework in Figure 1 illustrates the population, interventions, outcomes, and adverse effects that will guide the literature search and synthesis.

Figure 1. Analytic Framework



BMI = body mass index; ED = emergency department; KQ = Key Question; WC = Worker's Compensation; QOL = Quality of Life

IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

The criteria for inclusion and exclusion of studies are designed to identify studies that can answer the Key Questions and are based on the population, intervention, comparators, outcomes, timing, setting (PICOTs) are show in Table 1 and described in section II above. We do not repeat here all of the PICOTs information related to the inclusion/exclusion criteria.

Table 1. Eligibility criteria

PICOTs	Inclusion	Exclusion
Population	Employed adults (18 years of age or older)	Children and adolescents under age 18
Intervention	As defined above in PICOTs	All other interventions
Comparator	As defined above in PICOTs	No comparison; nonconcordant historical controls
Outcomes	As defined above in PICOTs	KQs 2, 3, 4: All other outcomes, such as measures of aerobic capacity (e.g., maximal oxygen consumption) or exercise performance (e.g., number of sit-ups performed); measures of self-efficacy; participation in specific health promotion or safety programs (that are separate from the intervention); economic evaluation outcomes (e.g., return on investment)
Timing	All KQs: Any duration of followup	None
Setting	All KQs: Studies conducted in any workplace setting in a developed country (“very high” human development index per the United Nations Development Programme) ²¹	Studies conducted in any other countries
Study designs	All KQs: Original research, including RCTs, nonrandomized controlled trials, prospective cohort studies with a concurrent control group KQ1: “Pre-post” cohort studies without a control group (in addition to the study designs listed above)	All other designs including case reports, case series, systematic reviews, nonsystematic reviews, studies with historical (rather than concurrent) control groups

KQ = Key Question; PICOTs = populations, interventions, comparators, outcomes, timing, and setting; RCT = randomized controlled trial.

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

We will systematically search, review, and analyze the scientific evidence for each Key Question (KQ). The steps that we will take to accomplish the literature review are described below.

To identify articles relevant to each KQ, we will begin with a focused MEDLINE® search on Total Worker Health (TWH) interventions by using a variety of terms, medical subject headings (MeSH), and major headings. Table 2 lists the relevant terms. We will also search the Cochrane Library, the Cochrane Central Trials Registry, and PsycInfo using analogous search terms. We will conduct quality checks to ensure that our searches identify known studies (i.e., studies highlighted in NIOSH’s TWH program materials). An experienced librarian familiar with systematic reviews will design and conduct all searches in consultation with the review team. We will ask the Technical Expert Panel for feedback on the search terms and strategy.

Table 2. Provisional MEDLINE® literature search terms

Category	Search Terms
Intervention	“total worker health” “Occupational Health”[Mesh] OR “Occupational Health Services”[Mesh] OR “Occupational Injuries”[Mesh] OR “Workplace”[Mesh] OR “worksite health” AND (“Health Promotion”[Mesh]) OR “Accident Prevention”[Mesh]) OR “Wounds and Injuries/prevention and control”[Mesh]
Limits	Humans English language Publication date 1990 to [date of search]

Our literature searches will include articles published between 1990 and 2015. A review of NIOSH’s TWH background documents, previously published narrative reviews, and our literature scan indicates that the majority of programs began after 1990. We will also check reference lists of the included studies and systematic reviews to confirm that earlier studies were not missed. The literature search will be updated concurrent with the peer review process.

We will search the “gray literature” for unpublished studies relevant to this review and will include studies that meet all the inclusion criteria and contain enough methodological information to assess risk of bias. Gray literature sources will include ClinicalTrials.gov and any scientific information packages received from Federal register notices or informational requests

Data Abstraction and Data Management: We will establish criteria to determine eligibility for inclusion and exclusion of abstracts in accordance with the KQs and the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.²² To ensure accuracy, all titles and abstracts will be reviewed independently by two reviewers. We will retrieve the full text for all citations deemed appropriate for inclusion by at least one of the reviewers. Each full-text article, including any articles that peer reviewers suggest or that may arise from the public posting process, will be independently reviewed for eligibility by two team members. Any disagreements will be resolved by consensus. We will maintain a record of studies excluded at the full-text level with reasons for exclusion and will include this list in our final report.

After we select studies for inclusion, we will abstract data into categories that include (but are not limited to) the following: study design, year of publication, work setting, geographic location, sample size, eligibility criteria, population characteristics, TWH intervention characteristics, organizational or employer characteristics, and outcomes relevant to each KQ as outlined in the previous PICOTs section. In addition, we will abstract data related to study funding source, risk of bias factors, and contextual factors that may influence the effectiveness of interventions. Relevant information that we will abstract for assessing applicability will include the characteristics of the population (e.g., occupation and demographic factors), work setting, and geographic setting. A second team member will verify abstracted study data for accuracy and completeness.

Assessment of Methodological Risk of Bias of Individual Studies: To assess the risk of bias (i.e., internal validity) of studies, we will use predefined criteria based on the *AHRQ Methods Guide for Comparative Effectiveness Reviews*. These include questions to assess selection bias, confounding, performance bias, detection bias, and attrition bias; concepts covered include those about adequacy of randomization, similarity of groups at baseline, masking, attrition, whether intention-to-treat analysis was used, method of handling dropouts and missing data, validity and reliability of outcome measures, and treatment fidelity).²²

In general terms, results from a study assessed as having 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 issues in design, conduct, or analysis) that may invalidate its results. We plan to exclude studies deemed high risk of bias from our main data synthesis and main analyses for KQ 2; we will include them only in sensitivity analyses.

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

Data Synthesis: We will summarize all included studies in narrative form and in summary tables that tabulate the important features of the study populations, design, intervention, outcomes, and results. We do not expect to be able to perform any meta-analysis because of the likely heterogeneity across populations, interventions, and outcomes of included trials. Nonetheless, we will consider performing meta-analyses where we have at least three unique studies of low or medium risk of bias that we deem to be sufficiently similar in population and to have the same comparison of interventions and the same outcomes. If meta-analysis seems appropriate in these circumstances, we will perform only random-effects model meta-analyses. We will look across trials to identify heterogeneity qualitatively any potential effect-modifying factors, such as age, work setting, and components of the included intervention. If clinical heterogeneity can be narrowed down to a small number of promising factors, we will consider these for subgroup analyses.

Grading the Strength of Evidence for Major Comparisons and Outcomes: We will grade the strength of evidence based on the guidance established for the Evidence-based Practice Center Program.²³ Developed to grade the overall strength of a body of evidence, this approach now incorporates five key domains: risk of bias (including study design and aggregate risk of bias), consistency, directness, and precision of the evidence, and reporting bias. It also considers other optional domains that may be relevant for some scenarios, such as plausible confounding that would decrease the observed effect and strength of association (i.e., magnitude of effect).

Table 3 describes the grades of evidence that can be assigned. Grades reflect the strength of the body of evidence to answer the KQs on the comparative effectiveness, efficacy, and harms of the interventions in this review. Two reviewers will assess each domain for each key outcome, and differences will be resolved by consensus. We will grade the strength of evidence related to all outcomes relevant to KQ 2.

Table 3. Definitions of the grades of overall strength of evidence

Grade	Definition
High	We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
Moderate	We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

Source: Berkman et al.²³

Assessing Applicability: We will assess the applicability of individual studies as well as the applicability of a body of evidence following guidance from the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.²⁴ For individual studies, we will examine conditions that may limit applicability based on the PICOTs structure. Some factors identified a priori that may limit the applicability of evidence include the following: sex of enrolled populations (e.g., few women may be enrolled in the studies), race or ethnicity of enrolled populations, work setting of enrolled populations (and associated occupational hazards), geographic setting, and availability of health insurance and other health-related employment benefits.

V. References

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VI. Definition of Terms

We will define important terms in the full report.

VII. Summary of Protocol Amendments

If we need to amend this protocol, we will give the date of each amendment, describe the change, and give the rationale in this section. We will not incorporate changes into the protocol.

VIII. Review of Key Questions

AHRQ did not post these key questions on the Effective Health Care Website for public comment. The key questions were developed as part of the National Institute of Health Office of Disease Prevention Pathways to Prevention workshop.¹⁹ The RTI-UNC EPC suggested minor revisions to the key questions after input from the Technical Expert Panel. This input is intended to ensure that the key questions are specific and relevant.

IX. Key Informants

This topic did not involve a Topic Refinement period; input was not solicited from Key Informants.

X. Technical Experts

Technical Experts constitute a multi-disciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes and identify particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicting opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore, study questions, design, and methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor do they contribute to the writing of the report. They have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts, and those who present with potential conflicts may be retained. The ARHQ Task Order Officer and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the draft report in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The final report does

not necessarily represent the views of individual reviewers. The EPC will complete a disposition of all peer review comments. The disposition of comments for systematic reviews and technical briefs will be posted on the AHRQ website 3 months after the publication of the evidence report.

Potential Peer reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than \$10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

XII. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than \$1,000 and any other relevant business or professional conflicts of interest. The EPC core team has no conflicts to disclose. Related financial conflicts of interest that cumulatively total greater than \$1,000 will usually disqualify EPC core team investigators.

XIII. Role of the Funder

This project was funded under Contract No. HHS A290201200008I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.