

# The Effectiveness of Health Coaching

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#### **PREFACE**

The VA Evidence-based Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of particular importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. QUERI provides funding for four ESP Centers, and each Center has an active University affiliation. Center Directors are recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Centers. The ESP is governed by a Steering Committee comprised of participants from VHA Policy, Program, and Operations Offices, VISN leadership, field-based investigators, and others as designated appropriate by QUERI/HSR&D.

The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

The ESP Coordinating Center (ESP CC), located in Portland, Oregon, was created in 2009 to expand the capacity of QUERI/HSR&D and is charged with oversight of national ESP program operations, program development and evaluation, and dissemination efforts. The ESP CC establishes standard operating procedures for the production of evidence synthesis reports; facilitates a national topic nomination, prioritization, and selection process; manages the research portfolio of each Center; facilitates editorial review processes; ensures methodological consistency and quality of products; produces "rapid response evidence briefs" at the request of VHA senior leadership; collaborates with HSR&D Center for Information Dissemination and Education Resources (CIDER) to develop a national dissemination strategy for all ESP products; and interfaces with stakeholders to effectively engage the program.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP CC Program Manager, at Nicole.Floyd@va.gov.

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#### **ABSTRACT**

**Background:** Chronic medical conditions are common among VA healthcare system users, with nearly 75% of VA users having 2 or more chronic conditions. Optimizing beneficial patient health behaviors can help improve outcomes associated with chronic medical conditions. Yet making any kind of healthy changes can be a daunting task for many patients, especially those with multiple chronic conditions. Health coaching is an emerging collaborative and patient-centered approach to health promotion that may be an effective tool to facilitate uptake of health behaviors among people with one or more chronic medical conditions.

This systematic review evaluated the effects of self-identified health coaching interventions among adults with chronic medical conditions on clinical, behavioral, and self-efficacy outcomes. We also explored if the intervention effects varied by program elements such as patient chronic disease status, intervention dose (*ie*, the number of coaching sessions), mode of coaching delivery, and individuals conducting health coaching (*eg*, healthcare providers, peers, health coaches). In collaboration with key stakeholders, we also explored if effects varied by concordance of health coaching intervention with an *a priori* list of key elements (*ie*, patient-centeredness, patient-determined goals, self-discovery process).

Methods: We conducted searches of MEDLINE (via PubMed), Embase, CINAHL, and PsycINFO for peer-reviewed, English-language, randomized controlled trials among adults (≥18 years of age) of interventions self-identified as health coaching. Because health coaching is a relatively new intervention approach, we limited the search to the year 2000 forward. We conducted article inclusion screening, data abstraction, and quality assessment based on predetermined criteria and through a duplicate process, with discussion to resolve discrepancies. We evaluated trial quality as low, unclear, or high risk of bias. Strength of evidence was summarized as high, moderate, low, or insufficient on two outcomes—HbA1c and weight as measured by change in BMI—that were judged to be the most important outcomes by VA stakeholder partners.

When meta-analysis was feasible, we computed summary effect estimates via standardized mean differences or mean differences in random-effects models with Knapp-Hartung confidence interval correction. Heterogeneity was measured with  $I^2$ . We grouped analysis based on active (eg, counseling) or inactive (eg, usual care, waitlist) comparator. When meta-analysis was not feasible, we synthesized qualitatively.

Results: We identified 2627 unique citations; 41 trials met eligibility criteria. Women comprised 65% of the population. Median age was 59.2 years. Of the 18 trials reporting race, the median was 58% white. Most studies recruited populations with type 2 diabetes (n=18). The remaining studies recruited patients with mixed diagnoses of diabetes and heart disease or renal disease (n=4), obesity (n=7), or heart disease only (n=4). Other trials addressed cancer (n=2), rheumatoid arthritis (n=2), systemic lupus erythematosus (n=1), multiple sclerosis (n=1), metabolic syndrome (n=1), or chronic medical conditions in general (n=1). The median trial size was 201 (range 32 to 1835 per trial). Most trials were conducted in the United States (61%). The overwhelming majority of included trials used inactive comparators (n=31). Only one trial was conducted in a VA setting with VA users. Study quality was not high. Over 50% of trials (n=21) received a grade of unclear risk of bias, while 34% of trials (n=14) received a grade of high risk of bias.

Compared with inactive comparators, health coaching had a statistically significant effect on HbA1c (MD -0.30; 95% CI -0.50 to -0.10); physical activity change (SMD 0.29; 0.15 to 0.43); weight as measured by BMI (MD -0.52; -0.91 to -0.14); dietary fat reduction (SMD -0.21; -0.31 to -0.10); and self-efficacy (SMD 0.41; 0.21 to 0.62). For the outcome of achieving or exceeding physical activity thresholds, health coaching showed a positive trend when compared with inactive controls, but it was not statistically significant (n=5 trials; SMD 0.33; 95% CI -0.54 to 1.19). Similarly, the effect of health coaching on diet adherence also was not significant when compared with an inactive comparator (SMD 0.05; 95% CI -0.08 to 0.19). Only change in physical activity (eg, step counts, minutes of activity) had sufficient studies to compare effects against trials with active comparators. When compared with active controls, physical activity change was not significant (SMD 0.17; -0.32 to 0.67). Many pooled estimates exhibited moderate to high statistical heterogeneity ( $I^2 \ge 50\%$ ). In qualitative syntheses, results were mixed or inconclusive for effects of health coaching on functional status, smoking cessation, and medication adherence. However, limited qualitative evidence in 2 identified trials suggests that coaching has a positive effect on total calorie reduction.

We rated the strength of evidence for the 2 key outcomes as follows. We found moderate strength of evidence for small decreases in HbA1c (MD -0.30; 95% CI -0.50 to -0.10) and small decreases in BMI (MD -0.52; 95% CI -0.91 to -0.14) when health coaching interventions were compared with inactive controls. We found insufficient strength of evidence for the impact of health coaching on HbA1c and BMI when compared with active control conditions.

We also explored potential sources of variability in treatment effects, including population characteristics, intervention dose, intervention delivery mode, type of individual conducting health coaching, and concordance with key elements of health coaching. None of these factors were robust predictors of variability in treatment effects.

Conclusions: These results suggest that health coaching interventions have the potential to produce small, positive, statistically significant effects on HbA1c decreases, BMI reductions, physical activity increases, dietary fat reductions, and self-efficacy improvements when compared with inactive controls. This trend did not extend to studies with more active comparators. Our results suggest that health coaching may be an effective self-management approach. Our results should be interpreted with caution. The relatively large number of studies with high or unclear risk of bias and moderate to high heterogeneity in pooled estimates limit certainty about the interpretation of our findings. Also, none of the moderators were strong drivers of variability in treatment effects, suggesting that moderate to high heterogeneity in pooled estimates may be driven by various intervention characteristics. We allowed studies to self-identify as health coaching interventions as opposed to applying a standard set of criteria and only including studies that met those criteria. Thus, variability in what the study authors considered health coaching may contribute to the overall variability in treatment effects.

While health coaching is a promising intervention modality, additional research is warranted on the impact of health coaching, especially in areas with limited identified literature (*eg*, medication adherence, smoking, physical function), and when compared with active comparators. Also, it is unclear whether health coaching offers additional advantages over other behavioral intervention modalities. Future research should employ innovative and rigorous study designs to explore the central elements that distinguish health coaching from other behavioral counseling and self-management approaches and how these unique elements have an impact on clinical and behavioral outcomes.





### **EVIDENCE REPORT**

#### INTRODUCTION

Chronic medical conditions such as diabetes, cardiovascular disease (CVD), and hypertension are highly prevalent among VA healthcare system users. Among VA patients, 72% have one or more chronic medical conditions (compared with 40% to 50% of other U.S. adults), and more than half have at least 2 chronic conditions. The management of chronic medical conditions is a time-consuming process for primary care physicians. One study found that it would take 828 hours per year to provide the required care for the top 10 chronic diseases. Thus, patients are increasingly being asked to take an active role in the self-management of their chronic medical conditions. Yet many patients leave a physician encounter confused about what to do to manage their own health due to conflicting and contradictory information. The self-management of the self-management of their chronic medical conditions.

Enhancing beneficial health behaviors (*eg*, medication adherence, diet, physical activity) holds great promise for improving outcomes associated with chronic medical conditions, but self-regulating changes in health behaviors can be difficult for patients. On average, only 50% of prescription medications are taken as instructed,<sup>5</sup> and only one in 5 adults gets the recommended minutes of physical activity each day.<sup>6</sup> For patients with multiple chronic conditions, recognizing how to prioritize among several possible health behavior changes and manage overall health can be a tremendous challenge.<sup>7</sup>

In recent years, health coaching has emerged as an innovative health promotion intervention approach to enhance patients' adherence to chronic disease self-management<sup>8</sup> with respect to improving modifiable health behaviors. While there is no consensus on how to define health coaching 10 or what elements constitute a health coaching intervention, several characteristics serve to define the approach. At its core, health coaching is a patient-centered, collaborative model grounded in theories of health behavior change in which a coach collaborates with the patient to identify goals and action plans that maximize personal well-being and overall health. The holistic approach includes solution-focused techniques like motivational interviewing, goalsetting, and problem-solving and has a central feature of patient empowerment toward autonomy. While a health coaching intervention may include some didactic patient education, the main thrust of health coaching interventions is to provide ongoing, bidirectional communication, motivational processes, support, and accountability to optimize self-management through building patient self-efficacy and skills acquisition. It is a modality grounded in the belief that patients are experts in their own life situations and can draw on these experiences to promote personal change. As such, health coaches work with patients to enhance activation and motivation to change by aligning health-related goals with the patient's personal values. 11

Most health coaches receive formal training in behavior change theory, motivational strategies, and communication techniques, but only a small proportion are trained therapists. While health coaching shares common elements with other intervention approaches such as patient education and disease management, it differs in its emphasis on both the overall approach and the process. Patient education and disease management tend to be more expert-directed, task-oriented, and focused on disease-specific content, whereas health coaching is conceptualized to be collaborative, client-centered, and more likely focused on the whole person. <sup>12</sup>



#### **METHODS**

#### **TOPIC DEVELOPMENT**

Improving the management of multiple chronic conditions continues to be a top priority for VA researchers and clinicians alike. <sup>13</sup> This evidence report was commissioned to examine the effectiveness of health coaching on changes in clinical health outcomes, health behaviors, and other key outcomes of interest to stakeholders. The report is intended to inform clinical practice decisions and develop guidelines on how best to incorporate the use of health coaching within the VA healthcare system. It is also intended to identify key program elements associated with variable intervention effects, including the patient groups most likely to benefit, the optimal dose (*ie*, the number and frequency of coaching sessions), the mode of coaching delivery, and the most effective types of people/professionals to conduct health coaching (*eg*, physicians, social workers, nurses, dieticians, peers). This report identifies gaps in evidence that warrant further research, which may help the Office of Patient Centered Care and Cultural Transformation (OPCC&CT) and the National Center for Health Promotion and Disease Prevention (NCP) prioritize future research projects.

The key questions (KQs) for this systematic review were developed after a topic refinement process that included a preliminary review of published peer-reviewed literature, consultation with internal partners and investigators, and consultation with content experts and key stakeholders at OPCC&CT and NCP.

The final KQs were:

- KQ 1: Among adults, what is the effectiveness of health coaching on
  - a. Clinical health outcomes (eg, HbA1c, blood pressure)
  - b. Patient health behavior (*eg*, physical activity, weight management, diet, smoking, medication adherence)
  - c. Self-efficacy
- KQ 2: Among adults, does the impact of health coaching vary by
  - a. Characteristics of the population (eg, type of chronic medical illnesses)
  - b. Dose of the intervention (eg, number and frequency of sessions, minutes of contact)
  - c. Mode of delivery (eg, individual visits vs group visits, face-to-face vs telephone)
  - d. Types of individuals conducting coaching interventions (*eg*, peers, nurses, health educators, health coaches)
  - e. Concordance with key elements of health coaching (*ie*, patient-centeredness, patient-determined goals, self-discovery process)

We followed a standard protocol for this review, and each step was pilot-tested to train and calibrate study investigators. The PROSPERO registration number is CRD42016036119.

#### **SEARCH STRATEGY**

In consultation with an expert librarian, we conducted searches of MEDLINE (via PubMed), Embase, CINAHL, and PsycINFO. Because health coaching is a relativity new intervention approach, we limited the search to the year 2000 forward. We evaluated the bibliographies of included primary studies and any systematic or nonsystematic reviews that were identified. We used a combination of MeSH keywords and selected free-text terms to search titles and abstracts. To ensure completeness, search strategies were also informed by search strategies recommended by the Cochrane Effective Practice and Organization of Care Group. To assess for publication bias, we searched ClinicalTrials.gov to identify completed but unpublished studies meeting our eligibility criteria, an indicator of possible publication bias. All citations were imported into 2 electronic databases (for referencing, EndNote® Version X7, Thomson Reuters, Philadelphia, PA; for data abstraction, DistillerSR; Evidence Partners Inc., Manotick, ON, Canada). The exact search strategies used are in Appendix A.

#### STUDY SELECTION

Using prespecified inclusion/exclusion criteria (Table 1), titles and abstracts of RCTs identified through our search were reviewed by 2 reviewers for potential relevance to the KQs. Articles included by either reviewer underwent full-text screening. At the full-text screening stage, 2 independent reviewers were required to agree on a final inclusion/exclusion decision and the rationale for this decision. Disagreements were resolved by discussion or by a third investigator. Articles meeting eligibility criteria were included for data abstraction.

Table 1. Inclusion and Exclusion Criteria

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Population	Adults 18 years of age and older selected for the presence of, or diagnosis of, or one or more chronic medical conditions	<ul> <li>Children</li> <li>Inpatient populations/long-term care or nursing home populations</li> <li>Patients with terminal illnesses</li> <li>Patients with primary mental health diagnosis</li> <li>Patients with risk factors for, but not diagnosis of, a chronic medical condition</li> </ul>

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Interventions	<ul> <li>Studies that self-identify primarily as coaching interventions (eg, health coaching, wellness coaching, peer coaching) and focus on improving outcomes related to a chronic medical condition or facilitating uptake of health behaviors, have more than one session or planned contact, and allow for 2-way communication between coach and participant</li> <li>For populations with mixed diagnoses or conditions (eg, mental and physical health conditions), at least 80% of the total population must consist of populations of primary interest</li> </ul>	Interventions defined primarily as:  Supportive or structured psychotherapies (eg, acceptance and commitment therapy or cognitive behavioral therapy focused on emotional or mental health concern)  Shared decision making  Medication management  Nurse-led protocols  Disease management only  Patient education only
Comparators	Usual care/standard of care, waitlist control     Other active comparator-focused	No controls
Outcomes	Clinical health outcomes that can be influenced by health behavior change (HbA1c, cardiovascular health, functional status outcomes) Patient behaviors: Physical activity Weight management Diet Smoking Medication adherence Self-efficacy	Any outcomes not listed
Setting	<ul> <li>Outpatient general medical settings (geriatrics, family medicine, general internal medicine, integrative medicine)</li> <li>Specialty medical settings for management of chronic medical conditions</li> <li>Community settings</li> </ul>	Intervention delivered primarily in hospital inpatient setting
Study design	Randomized controlled trials (RCTs), n >20 with at least 6-month outcomes	<ul> <li>Not a clinical study (eg, editorial, nonsystematic review, letter to the editor, case series)</li> <li>Nonrandomized or uncontrolled clinical study</li> <li>Prospective and retrospective observational studies</li> <li>Interrupted time-series studies</li> <li>Measurement or validation studies</li> </ul>
Publication type	<ul><li>English-language only</li><li>Peer-reviewed articles</li><li>Published from 2000 forward</li></ul>	Non-English articles     Abstracts only



#### DATA ABSTRACTION

Data from published reports were abstracted into a customized DistillerSR database by one reviewer and overread by a second reviewer. Disagreements were resolved by discussion or by a third investigator. Data elements included descriptors to assess applicability, quality elements, intervention/exposure details, and outcomes. Each included primary article was abstracted for date of publication, sample size, location of study, and key outcomes measured (Appendix B). Key characteristics abstracted were participants' age, sex, and chronic medical illness status. We collected details about the coaching intervention such as the number and frequency of sessions, mode of session delivery, type of provider conducting coaching intervention (eg, peer, nurse), whether there was collaboration with a primary care team, communication (eg, motivational interviewing) or theoretical orientation (eg, social cognitive theory, self-determination theory), training of the coach, content of coaching calls (eg, goal-setting, problem-solving, health education, self-monitoring). Multiple reports from a single study were treated as a single data point.

#### **QUALITY ASSESSMENT**

Quality assessment was done by the researcher abstracting or evaluating the included article; this initial assessment was overread by a second, highly experienced reviewer. Disagreements were resolved between the 2 reviewers or, when needed, by arbitration from a third reviewer.

We used the key quality criteria described in the Cochrane Collaboration Risk of Bias Tool. This tool was designed to evaluate the risk of bias in RCTs. The tool evaluates 6 domains: (1) adequacy of random sequence generation, (2) allocation concealment, (3) blinding of participants and study personnel, (4) incomplete outcome data, (5) reporting bias due to selective outcome reporting, and (6) other forms of bias such as differences in relation to baseline measures, reliable primary outcomes or protection against contamination. The Cochrane Collaboration provides guidelines to score each item. Each domain is evaluated as low risk of bias, high risk of bias, or unclear risk of bias (Table 2). To draw conclusions about the overall risk of bias within trials, we summarized assessments across items in the tool for each outcome within each trial and used the approach outlined below to formulate overall risk of bias for key outcomes separately. Appendix C contains a table of quality assessment responses for the included studies.

Table 2. Approach to Formulating Summary Risk of Bias for Each Outcome Across Domains

Risk of Bias	Interpretation	Criteria
Low risk of bias	Bias, if present, is unlikely to alter the results seriously	Adequacy of random sequence generation, allocation concealment, and blinding scored as "low risk of bias" and no important concerns related to the other domains
Unclear risk of bias	A risk of bias that raises some doubts about the results	One or 2 domains are scored "not clear" or not done
High risk of bias	Bias may alter the results seriously	More than 2 domains are scored as "not clear" or not done

#### **DATA SYNTHESIS**

We summarized the primary literature by abstracting relevant data. We developed a summary table describing intervention and control conditions and key outcomes. We then determined the feasibility of completing a quantitative synthesis (*ie*, meta-analysis) to estimate summary effects. Feasibility depends on the volume of relevant literature, conceptual homogeneity of the studies, and completeness of results reporting. We aggregated outcomes when there were at least 3 studies with the same outcome, based on the rationale that one or 2 studies do not provide adequate evidence for summary effects. If meta-analyses were feasible, we explored the possibility of conducting subgroup analyses to explore the consistency of effects across populations and key intervention components. Because subgroup analyses that involve indirect comparisons (across studies) are subject to confounding, we interpreted results of these moderator analyses cautiously.

Six trials had more than 2 arms, and one trial used a nested 2x2 design.<sup>16</sup> As comparisons with usual care were the most common across other trials, we prioritized these comparisons for quantitative synthesis. If more than one active arm was a coaching intervention, we prioritized the arm with the most intensive dose (eg, 20 vs 10 sessions) or delivery mode (in-person vs telephone) coaching-only arm for quantitative analysis. We qualitatively synthesized other relevant health coaching comparisons with more active comparators. The study with a  $2x2^{16}$  design assessed the separate and combined impact of a physician-focused intervention and a patient-focused coaching intervention. For this study, we selected the comparisons between exposure to the patient-focused intervention and usual care control, as this was the comparison that most directly assessed the isolated impact of health coaching.

When quantitative synthesis was possible, we combined continuous outcomes using differences in follow-up means for HbA1c and body mass index (BMI) outcomes and standardized follow-up mean differences (SMD) for physical activity, diet, and self-efficacy outcomes in a random-effects model with the Knapp-Hartung correction for summary standard errors. For KQ 1, we stratified analysis by comparator type of active (eg, counseling, another form of coaching, attention control) or inactive (eg, waitlist, usual care). For KQ 2, we explored potential sources of heterogeneity by key design factors including characteristics of the population (eg, chronic medical illness status), dose of the intervention (ie, number of planned sessions), primary mode of intervention delivery (eg, telephone, in-person sessions), type of coach (eg, certified health coach, peer, healthcare professional), and concordance of health coaching interventions with an a priori list of key elements (see below for more details). We evaluated for statistical heterogeneity using visual inspection and Cochran's Q and I² statistics. Publication bias was assessed using findings from the ClinicalTrials.gov search and using funnel plots (if >10 studies in an analysis).

When quantitative synthesis was not feasible, we analyzed the data qualitatively. We gave more weight to the evidence from higher quality studies with more precise estimates of effect. A qualitative synthesis focuses on documenting and identifying patterns of the intervention across outcome categories. We analyzed potential reasons for inconsistency in treatment effects across studies by evaluating differences in the study population, intervention, comparator, and outcome definitions.



#### PRIORITIZATION OF HEALTH COACHING KEY ELEMENTS

The potential key elements for health coaching, such as accountability, consistent coaching relationship, content education, patient-centeredness, patient-determined goals, and use of a self-discovery process, have been described in a systematic review by Wolever et al.<sup>14</sup> However, the relative importance of these elements to each other has not been defined. In order to determine which elements may be key drivers of effects, we used a forced-rank methodology<sup>17</sup> whereby we presented the set of 6 crucial elements from Wolever et al<sup>14</sup> to stakeholders, the members of our technical expert panel, and content expert research team members for ranking. The top 3 elements from this initial ranking were retained, followed by discussion and reranking to designate a proposed main driver of the effect of health coaching.

Our stakeholders included representatives from the National Center for Health Promotion and Disease Prevention and the Office of Patient-centered Care and Cultural Transformation. The technical expert panel included faculty members from the Duke School of Nursing and Vanderbilt University Medical Center; a core investigator from the VA Portland Healthcare System; and representatives from the Pacific Institute for Research and Evaluation and from Healthwise<sup>®</sup>.

After the first round of voting, patient-centeredness, patient-determined goals, and use of a self-discovery process emerged clearly as the "key" elements of health coaching, with 8 to 9 votes each, while the other 3 elements received 2 to 3 votes each. After the second round of voting, patient-centeredness was proposed to be the main driver of health coaching, receiving 12 votes, while both patient-determined goals and use of self-discovery received only 8 votes. Thus, our final key elements were (1) patient-centeredness as the proposed main driver, (2) patient-determined goals, and (3) use of a self-discovery process.

To create a concordance score, 2 investigators independently assessed if the 3 prioritized elements were present or not. A study was given 1 point for demonstrated use of patient-determined goal or use of self-discovery process and 2 points for patient-centeredness, as this was rated as the main driver of coaching effects by our stakeholders and content experts. Thus, a study could receive a concordance score ranging from 0 to 4. Informed by the work of Wolever et al, <sup>14</sup> we operationalized the key elements of health coaching as follows:

- Patient-centeredness: Was the coaching patient-centered, whereby coaching strategies and
  processes were tailored to the individual's specific needs, concerns, circumstances, priorities,
  or readiness to change—or was the coaching applied uniformly without regard to individual
  differences?
- Patient-determined goals: Did patients choose their own change goals and action steps as a target of the coaching—or were their goals preset or created by a professional?
- *Use of self-discovery*: Did the coaching include a process of discovery or active learning (*eg*, motivational interviewing) to increase patient awareness through examining strengths, values, and assumptions—or was the coaching instructional?



#### RATING THE BODY OF EVIDENCE

The strength of evidence (SOE) for each key question was assessed using the approach described in AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*, <sup>18</sup> and we focused on the key outcomes identified by our partners. In brief, this approach required assessment of 4 domains: risk of bias, consistency, directness, and precision (Table 3).

**Table 3. Strength of Evidence Required Domains** 

Domain	Rating	How Assessed
Quality (risk of bias)	Good Fair Poor	Assessed primarily through study design (randomized controlled trial vs observational study) and aggregate study quality
Consistency	Consistent Inconsistent Unknown/not applicable	Assessed primarily through whether effect sizes are generally on the same side of "no effect," the overall range of effect sizes, and statistical measures of heterogeneity
Directness	Direct Indirect	Assessed by whether the evidence involves direct comparisons or indirect comparisons through use of surrogate outcomes or use of separate bodies of evidence
Precision	Precise Imprecise	Based primarily on the size of the confidence intervals of effect estimates, the optimal information size and considerations of whether the confidence interval crossed the clinical decision threshold for using a therapy

Additional domains were used when appropriate: coherence, dose-response association, impact of plausible residual confounders, strength of association (magnitude of effect), and publication bias. These domains were considered qualitatively, and a summary rating was assigned after discussion by 2 reviewers as high, moderate, or low strength of evidence. In some cases, high, moderate, or low ratings were impossible or imprudent to make. In these situations, a grade of insufficient was assigned. This 4-level rating scale consists of the following definitions:

- High—High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- Moderate—Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low—Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- · Insufficient—Evidence either is unavailable or does not permit estimation of an effect.

#### **PEER REVIEW**

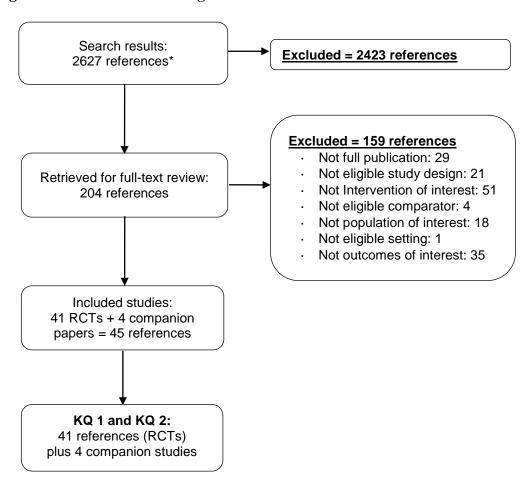
This report was reviewed by technical experts and clinical leadership. A transcript of their comments and our responses is provided in Appendix D.

#### **RESULTS**

#### LITERATURE FLOW

Figure 1 shows the flow of articles through the search and review process. The literature search identified 2627 unique citations from a combined search of MEDLINE® (via PubMed®), Embase, CINAHL and PsycINFO. After applying inclusion and exclusion criteria at the title-and-abstract screening level, 205 full texts were retrieved for further review. Of these, 41 randomized controlled trials (RCTs) were retained for data abstraction. All 41 RCTs addressed both KQ 1 and KQ 2. Appendix B presents a study characteristics table detailing all 41 eligible RCTs included in this report.

Figure 1. Literature Flow Diagram



<sup>\*</sup> Search results from PubMed (875), CINAHL (1239), Embase (450), and PsycINFO (63) were combined.

#### CHARACTERISTICS OF INCLUDED STUDIES

Across the 41 included trials, the number of health coaching sessions ranged from 3 to 156 with a median of 12. Primary mode of coaching delivery was by phone in 52% of trials, followed by 28% in-person (n=9 individual and 4 group). Other coaching delivery modes were mixed (n=4), video (n=2), and web (n=2). Only one trial used a "certified" health coach. Fifty percent of trials used healthcare providers (*eg*, registered nurses) for coaches; 14% used peers; 11% were behavioral health providers (*eg*, social workers), and another 23% used other nonprofessionals who did not qualify as "peers." In total, 37% of trials did not report the level of interventionist training. For the studies that reported level of training, regimes varied considerably across studies in detail, scope, and duration. Of the 3 prioritized key elements of coaching examined in this report, patient-centeredness was the most prevalent (68% of trials), followed by patient identification of goals (58.5% of trials) and the self-discovery process (46%). Only 14 trials contained all 3 key elements. Ten trials had active comparator arms (*eg*, another mode of coaching, an intensive noncoaching program), while the other 31 used inactive comparators (*eg*, waitlist, usual care). A search of ClinicalTrials.gov identified 2 completed but unpublished trials that we believe would meet our inclusion criteria, revealing a small degree of publication bias.

Most studies recruited populations with type 2 diabetes (n=18). The remaining studies recruited patients with mixed diagnoses of diabetes and heart disease or renal disease (n=4), obesity (n=7), or heart disease only (n=4). Other trials addressed cancer (n=2), rheumatoid arthritis (n=2), systemic lupus erythematosus (n=1), multiple sclerosis (n=1), metabolic syndrome (n=1), or chronic conditions in general (n=1). The 41 trials included 11,390 subjects (average 278, median 201, range 32 to 1835 per trial). Of the 36 trials reporting completion rates, all were above 75% except one, which was 64%. All trials reported average age, which ranged from 20.5 to 69.6 years with a median of 59.2 years. In the 40 trials reporting gender, women averaged 65% (range 15% to 100%). Race was not reported in 56% of the trials. Of the 18 trials reporting race, median was 58% white (range 0% to 99%).

Studies were conducted between 2002 and 2016 in 9 countries: 61% in the United States, 17% in Europe, and 12% in Australia. The majority (93%) were funded by government or foundations. Only one of these was a VA trial. The setting was primary care (n=18), specialty clinic (n=9), community (n=7), or other setting (n=7; eg, university, workplace). Duration of the active intervention period was reported in all but one trial<sup>21</sup> and ranged from 12 to 104 weeks (median 33 weeks) with 80% of studies having an active intervention period of 6 months or longer. Only 15% trials (n=6) had a grade of low risk of bias. Over 50% of trials (n=21) received a grade of unclear risk of bias, while 34% of trials (n=14) received a grade of high risk of bias.

Table 4 describes the intervention and comparators for the 41 RCTs in alphabetical order by author. We present detailed findings following the table, organized by KQ and then by outcome of interest as follows:

- KQ 1a—Clinical health outcomes: HbA1c (n=20), cardiovascular health (n=6), and functional status (n= 2)
- KQ 1b—Patient health behaviors: physical activity (n=17), weight management (n=20), diet (n=10), smoking (n=2), and medication adherence (n=3)
- KO 1c—Self-efficacy (n=8)
- KQ 2—Same outcomes as KQ 1, along with variations by 5 key moderators of interest:

- o KQ 2a—Population characteristics
- o KQ 2b—Dose of intervention
- o KQ 2c—Mode of delivery
- o KQ 2d—Type of individual conducting the coaching intervention
- o KQ 2e—Concordance with key elements

**Table 4. Health Coaching Intervention Characteristics** 

Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Annesi, 2011 <sup>22</sup> Obesity 137	Six 1-hour individual meetings with YMCA "Coach Approach" trained wellness specialist + at-home exercise prescription (3/week for 24 weeks for total of 72 sessions)	<ul> <li>Patient- centeredness</li> <li>Patient- determined goals</li> <li>Use of self- discovery process</li> </ul>	6 individual meetings with standard- trained fitness specialist + 72 at home exercise sessions
Appel, 2011 <sup>23</sup> Obesity 415	Coaching in-person (group/individual) weekly for first 12 weeks, monthly (group/individual) next 12 weeks, then either in-person or phone for last 72 weeks by trained, supervised health professional + website and email	<ul> <li>Patient- centeredness</li> <li>Patient- determined goals</li> <li>Use of self- discovery process</li> </ul>	(1) Coaching support delivered remotely by phone, study-specific website, and e-mail (2) Self-directed weight management using website
Blackberry, 2013 <sup>24</sup> Type 2 diabetes 437	1 in-person baseline assessment, then 8 structured phone sessions on self-management of diabetes with coaching by trained, supervised general practice nurse; written session summaries provided to patient and primary care physician	Use of self- discovery process	After 1 in-person baseline assessment, usual care was provided including referrals to dieticians and other diabetes specialists
Bostrom, 2016 <sup>25</sup> Systemic lupus erythematosus 32	(1) 0-3 months: Individual, inperson 1-hour coaching by physiotherapist at study start, 6 weeks, and 12 weeks; general education, supervised aerobic exercise, loan and use of heart rate monitor, and use of physical activity diary (2) 4-12 months: Some physical activity supervision, heart rate monitor, and diary	None	Usual care at rheumatology clinic, but patients in control group were asked not to change their activity level during the study

Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Brodin, 2008 <sup>26</sup> Rheumatoid arthritis 228	Phone support after 1 week, moving to once monthly by physical therapist coach; physical function tests every 3 months to encourage adherence to graded activity goals, feedback given	Patient- determined goals	Usual care (no description given other than "control group")
Browning, 2014 <sup>27</sup> Type 2 diabetes 100	Heath coaching by nurse via in-person + phone (both 2/month for first 3 months) diminishing over next 9 months; maximum contact was 19 phone and 18 in- person sessions	<ul> <li>Patient- centeredness</li> <li>Use of self- discovery process</li> </ul>	Usual care provided by family physician where patients were typically referred to diabetes specialists or to Traditional Chinese Medicine practitioners
Cinar, 2014 <sup>28</sup> Type 2 diabetes 186	In addition to standard health education, 2 in-person individual visits + single 10-to 20-minute phone call within first 3 weeks; 1 in-person + 1 call in next 6 months; 1 in-person + 1 call in last 6 months, for up to 7 total contacts with the behavioral health specialist coach	Patient- centeredness	Health education consisting of 3 seminars on oral health and diabetes management
Damschroder, 2014 <sup>29</sup> Obesity 481	ASPIRE-Group: Coaching via in-person 90-minute group sessions with a specially trained lifestyle coach 1/week for 3 months, then 2/month for 6 months, then 60-minute sessions 1/month for last 3 months	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	(1) ASPIRE-Phone: Coaching via phone for 30 minutes, 1 time/week for 3 months, then 20 minutes for remaining time (2 times/month for 6 months decreasing to 1 time/month for last 3 months) (2) Standard VA MOVE! program
Frosch, 2011 <sup>21</sup> Type 2 diabetes 201	Phone coaching by trained nurse diabetes educator, 5 sessions total: first session for 60 minutes; sessions 2-3 for 30 minutes, sessions 4-5 for 15 minutes	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Education brochure on diabetes management; no other strategies employed
Glasgow, 2003 <sup>30</sup> Type 2 diabetes 320	Internet-based basic information + either (1) tailored self-management (computer-mediated access to trained professional coach approximately twice weekly or (2) peer support via online forum and newsletters	<ul><li>Patient- centeredness</li><li>Patient- determined goals</li></ul>	In-home training to use website providing chronic disease education without additional support

Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Hawkes, 2013 <sup>31</sup> Colorectal cancer 410	11 health coaching sessions biweekly for 5 months via phone by nurse, behavioral specialist, or health educator (average duration of call, 31.5 minutes) + handbook + motivational postcards + pedometer	<ul> <li>Patient- centeredness</li> <li>Patient- determined goals</li> <li>Use of self- discovery process</li> </ul>	Usual care + educational brochures on understanding colorectal cancer, cutting cancer risk, diet, and physical activity + quarterly mailed educational newsletter
Holland, 2005 <sup>32</sup> Mixed (at least one chronic condition, unspecified) 504	In-person meeting with nurse at baseline and 6 months, minimum 4 health coaching calls in between, 12 monthly newsletters, and fitness program; if depressed, patients also met with social worker	· Patient- centeredness	Usual care; controls were not recontacted by the program until the anniversary date of their initial interview for follow-up
Karhula, 2015 <sup>33</sup> Mixed (type 2 diabetes and cardiovascular) 250	One coaching phone call from employee trained in Pfizer coaching model every 4-6 weeks (target=12 total); length of call approximately 30 minutes and emphasized problem-solving skills + monitoring of weight, blood glucose, SBP, and/or step count dependent on diagnosis via mobile application	None	Usual care; no further details or description of control group given
Kim, 2015 <sup>34</sup> Type 2 diabetes 209	Six 2-hour group sessions over 6 weeks, then monthly coaching calls for 1 year from trained nurses or community health workers; calls ranged 15-45 minutes	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Waitlist; no further details given
Knittle, 2015 <sup>35</sup> Rheumatoid arthritis 78	2 in-person, individual coaching sessions with rheumatology nurse, 40-60 minutes, at weeks 4 and 5; 3 followup phone calls, 20 minutes, weeks 6, 12, and 18	Patient-     determined goals     Use of self-     discovery     process	Education via 1 in- person group session with nurse

Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Lin, 2013 <sup>16</sup> Hypertension 574	Weekly small groups for 20 weeks with trained health educators and dieticians + manual; strategies to manage weight and blood pressure via DASH diet, increase exercise; and coaching strategies; during and after group intervention, a peer educator phoned participants monthly for a total of 18 calls	Patient-     determined goals     Use of self-     discovery     process	Usual care was an individual visit with interventionist to receive advice + written materials on lifestyle modification for blood pressure control consistent with JNC-7 guidelines
Luley, 2014 <sup>36</sup> Metabolic syndrome 184	1 basic education session + monthly health coaching call from trained physician or nurse, each approximately 20 minutes + accelerometer (data transmitted to coach as basis for phone calls)	None	1 basic education session that included an explanation of importance of physical activity and diet
Ma, 2013 <sup>37</sup> (Companion study, Azar, 2013 <sup>38</sup> ) Obesity 241	Lifestyle Balance of 2 weekly, in-person group sessions (90-120 minutes) using goal-setting, with food tastings and 30-45 minutes of guided exercise led by coachdietician followed by 12-month maintenance phase; personalized email from coach monthly	· Patient- determined goals	(1) Self-led via DVD and email correspondence with coach/RD that used goal-setting, self-monitoring, and chronic disease education (2) Usual care; no further details given
McMurray, 2002 <sup>39</sup> End-stage renal disease with type 1 or 2 diabetes 83	Minimum of monthly (for peritoneal patients) in- person, individual sessions with diabetes care manager for motivational coaching; weekly contact as needed by phone with manager, social worker, registered dietician, or registered nurse to cover self-management and diabetes care; maximum of 3 times/week (for hemodialysis patients) for 12 months	None	Usual care at a standard dialysis unit
Nishita, 2013 <sup>40</sup> Type 2 diabetes 190	Average of ten 1-hour in- person, individual sessions with certified health coach and four 45-minute sessions with pharmacist over intervention year	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Usual care

Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Patja, 2012 <sup>41</sup> Mixed (congestive heart failure and type 2 diabetes) 1129	Monthly phone calls with nurse coach (initial duration averaging 60 minutes, decreasing to 30 minutes over time); call completion averaged 10-11 calls over year; optional follow-up calls were rarely used	· Patient- determined goals	Usual care
Pearson, 2013 <sup>19</sup> (Companion study, Pearson 2012 <sup>42</sup> ) Obesity 45	Phone coaching sessions with certified health coach 1/week for 12 weeks; average length of call was 45 minutes	<ul> <li>Patient- centeredness</li> <li>Patient- determined goals</li> <li>Use of self- discovery process</li> </ul>	Scripted education- based phone lessons using cognitive behavioral therapy principles from LEARN manual 1/week for 12 weeks; average length of call was 30-45 minutes
Pinto, 2015 <sup>43</sup> Breast cancer 76	Health coaching by peer educator via phone 1/week for 12 weeks; average call length was 18 minutes + pedometer + heart rate monitor + physical activity tipsheets	· Patient- centeredness	Attention control: phone contact with peer educator 1/week for 12 weeks, but topics centered on breast cancer, not physical activity
Ruggiero, 2010 <sup>44</sup> Type 2 diabetes 100	2 in-person, individual contacts (<30 minutes) with certified medical assistant trained in diabetes self-care coaching at baseline and 3 months + 4 monthly phone contacts (<15 minutes) in between clinic visits	· Patient- centeredness	Usual care with physician + basic diabetes education handbook developed by health system staff
Ruggiero, 2014 <sup>20</sup> Type 2 diabetes 266	Quarterly in-person, individual coaching sessions with specially trained certified medical assistants for 30 minutes at clinic appointments; up to 8 monthly phone calls, 15 minutes, between in-person contacts	Patient-     centeredness     Patient-     determined goals	Enhanced treatment as usual; quarterly physician check-ups; referrals to specialty care (eg, podiatrist, endocrinologist) when necessary; basic education provided by "Diabetes: You're in Control" educational booklet
Sacco, 2009 <sup>45</sup> Type 2 diabetes 62	Coaching call weekly for 3 months (from supervised psychology undergraduate), then every other week for 3 months; average duration of initial call was 54 minutes decreasing to 15-20 minutes	Patient-     centeredness     Patient-     determined goals	Control group received treatment as usual from a board-certified endocrinologist

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Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Safford, 2015 <sup>46</sup> Type 2 diabetes 360	1-hour group diabetes education class + one 5-10 minute individual counseling session to go over baseline "diabetes report cards," then peer coaches phoned weekly for the first 2 months and at least monthly for the next 8 months	<ul> <li>Patient- centeredness</li> <li>Patient- determined goals</li> <li>Use of self- discovery process</li> </ul>	1-hour group diabetes education class + 5-10 minute counseling session on a "diabetes report card" showing baseline labs at enrollment
Sandroff, 2014 <sup>47</sup> Multiple sclerosis 76	Coaching (discipline of coach not reported) via internet and 15, one-on-one video sessions (eg, Skype) for 6 months decreasing in frequency over time (from weekly to monthly)	· Patient- determined goals	Waitlist
Sherwood, 2010 <sup>48</sup> Obesity 63	2 active arms (same intervention for different durations: 10 sessions or 20 sessions) providing weekly telephone calls with coach (discipline not reported) lasting about 10-20 minutes + pedometer + logbook; calls followed a prescribed sequence in study manual adapted to fit into 10 or 20 lessons	Not reported	Self-directed program participants were sent copy of manual, pedometer and logbook but were not recontacted until time for follow-up measures
Thom, 2013 <sup>49</sup> (Companion study, Moskowitz, 2103 <sup>50</sup> ) Type 2 diabetes 299	12-14 sessions of coaching by a peer educator (individual or phone at discretion of subject) with goals of phone contact at least twice/month and 2 or more in-person contacts over 6 months	· Patient- centeredness	Usual care included all services normally available, including a nutritionist and diabetes educator via referral from their primary care physician
Turner, 2012 <sup>51</sup> Hypertension 280	Phone calls every other month at 1, 3, and 5 months (duration not reported); on alternate months (2 and 4), office-based, in-person, individual counseling sessions (15-30 minutes each) with a peer educator as coach	Patient-     centeredness     Use of self-     discovery     process	Usual care at urban academic general medicine practices
Vale, 2002 <sup>52</sup> Cardiovascular disease 219	5 coaching phone calls from dietician, with first call within 2 weeks of randomization; then 3 calls, one every 6 weeks; the fifth call at 24 weeks (to schedule the 6-month assessment); duration of calls varied	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Usual care; no further details given



Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Vale, 2003 <sup>53</sup> Coronary artery disease, cardiovascular disease 792	5 coaching phone calls from nurse or dietician, with first call within 2 weeks of randomization; then 3 calls, one every 6 weeks; the fifth call at 24 weeks (to schedule the 6-month assessment); duration of calls varied	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Usual care; no further details given
Van der Wulp, 2012 <sup>54</sup> Type 2 diabetes 119	3 in-person, individual health coaching sessions, monthly, with trained peer educator using goal setting; duration of session not reported	Patient-     centeredness     Patient-     determined goals	Usual care from general practitioner based on the Dutch guidelines for type 2 diabetes
Varney, 2014 <sup>55</sup> Type 2 diabetes 94	Initial coaching call within 2 weeks of randomization followed by at least monthly phone calls (range 4-9 sessions) from dietician coach; duration average 45 minutes initially, then 20 minutes for follow-up calls	· Patient- centeredness	Control group accessed usual care services, including a diabetes clinic staffed by endocrinologists, diabetes educators and dietitians; patients typically attend the clinic at least monthly, with general practitioner visits occurring as needed
Wadden, 2011 <sup>56</sup> Obesity 390	(1) Coaching only: primary care visits plus 10-15 minute in-person, individual coaching sessions; 2 during the first month, then monthly for 11 months with a trained medical assistant; in months 13-24, coaching could be done by phone every other month (2) Enhanced coaching: as above + choice of meal replacements or weight loss medication	None	Usual care consisting of quarterly primary care visits that included education about weight management for 5-7 minutes each visit
Wayne, 2015 <sup>57</sup> Type 2 diabetes 131	Weekly health coach sessions + exercise education program with smartphone wellness mobile application; components included support for health goals and goal achievement; self-monitoring; discussion of meals, exercise, blood glucose and mood; duration of session 37 (± 22) minutes/week; also health coach co-monitored patient's input to mobile application	Patient-     centeredness     Patient-     determined goals	Weekly health coach sessions + exercise education program without smartphone application; components included support for health goals and goal achievement; self-monitoring; discussion of meals, exercise, blood glucose, and mood; session duration 39 (±28) minutes/week



Study Condition N Patients	Intervention	Key Health Coaching Elements	Comparator
Whittemore, 2004 <sup>58</sup> Type 2 diabetes 53	6 in-person, individual coaching sessions with a trained nurse: first 3 every 2 weeks; then 2 monthly; last session 3 months after first 5 sessions with phone contacts in between sessions 5 and 6	Patient-     centeredness     Patient-     determined goals	Standard diabetes care, defined as regular visits with a primary care physician at approximately 3- to 4-month intervals
Willard-Grace, 2015 <sup>59</sup> (Companion study, Thom, 2015 <sup>60</sup> ) Mixed (type 2 diabetes, hypertension, elevated lipids) 441	5 in-person, individual coaching sessions at baseline, 3, 6, 9, and 12 months with a trained medical assistant as well as monthly follow-ups by phone; total 16 sessions	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Patients randomized to usual care had access to any resources available at the clinic, including visits with their clinician, diabetes educators, nutritionists, chronic care nurses, and educational classes
Wolever, 2010 <sup>61</sup> Type 2 diabetes 56	8 calls weekly for first 2 months, then 4 calls biweekly for 2 months; final call 1 month later for total of 14, 30-minute sessions with a trained social worker or medical assistant in psychology coach	Patient-     centeredness     Patient-     determined goals     Use of self-     discovery     process	Usual care; randomized to the control group received no materials or correspondence during the 6-month period
Young, 2014 <sup>62</sup> Type 2 diabetes 101	1 in-person, individual session with a nurse coach followed by 5 health coaching sessions via phone or video-conferencing, about once every 2 weeks; average duration of sessions was 30 minutes	<ul> <li>Patient- centeredness</li> <li>Patient- determined goals</li> <li>Use of self- discovery process</li> </ul>	Usual care consisted of the services and care available at the rural clinic where the participant received healthcare

# **KEY QUESTION 1: Among adults, what is the effectiveness of health coaching on**

- a. Clinical health outcomes (eg, HbA1c, blood pressure)
- b. Patient health behaviors (eg, physical activity, weight management, diet, smoking, medication adherence)
- c. Self-efficacy

#### **Key Points**

- Results were mixed for the impact of health coaching on a variety of clinical health outcomes. Health coaching demonstrated a small, positive, statistically significant effect on change in HbA1c (-0.30; 95% CI -0.50 to -0.10) compared with an inactive comparator. These findings did not hold when compared with active comparators. For other outcomes related to cardiovascular disease and functional status, results were inconsistent.
- For trials that reported the impact of health coaching on patient health behaviors, results also were inconsistent:
  - O Physical activity: We found a small, positive, statistically significant effect of health coaching on physical activity measured as a continuous variable in steps or minutes compared with an inactive control; when compared with active controls, the estimate was not significant. There was no difference between groups in studies that measured physical activity as reaching or exceeding some threshold.
  - Weight management: We found a small, positive, statistically significant effect of health coaching on reductions in BMI compared with an inactive control. Only 2 studies had active comparators and neither of these had statically significant effects.
  - O *Diet:* There were consistent small, positive effects of health coaching on decreasing fat intake in quantitative analysis and total calories in qualitative synthesis. Results were mixed for any effect of health coaching on fruit and vegetable intake, and only one study found a positive effect on diet adherence.
  - o *Smoking:* Only 2 trials measured the impact of health coaching on smoking behavior; smoking cessation was only one of a number of health behaviors addressed in both trials. Neither trial found an effect of health coaching on self-reported smoking cessation.
  - o *Medication adherence:* Three trials examined the impact of health coaching on medication adherence outcomes, and only one of these found that health coaching was associated with a significant improvement in medication adherence.
- For self-efficacy, when stratified by type of comparator, a statistically significant, small-to-moderate positive effect was found for health coaching interventions on self-efficacy when compared with inactive controls. Only one study compared health coaching with an active control. This effect size was also positive and statistically significant.



- A high risk of bias (ROB) and heterogeneity limit certainty about the interpretation of our findings.

For KQ 1, we present detailed findings on the effects of health coaching on clinical health outcomes (KQ 1a), patient health behaviors (KQ 1b), and self-efficacy (KQ 1c).

#### **Detailed Findings for Clinical Health Outcomes (KQ 1a)**

In this section, we describe findings by effects on HbA1c, cardiovascular health (systolic blood pressure, cholesterol), and functional status.

#### Effects on HbA1c

Twenty of the eligible RCTs examined the impact of health coaching on HbA1c in patients with diabetes. <sup>20,21,24,27,28,30,33,34,39-41,44-46,49,55,57-59,61</sup> Table 5 summarizes key elements of the 20 studies.

#### Table 5. Evidence Profile of Studies Reporting Change in HbA1c

Number of trials: 20 published 2002-2015.

Number of participants: 5850 total (average/trial=308, range 53 to 1835).

**Setting:** Most participants were recruited from primary care (n=10); remaining studies were conducted in a variety of specialty care settings or recruited directly from the community.

**Countries:** 6 countries were represented (Australia, Canada, China, Finland, Turkey, and USA; 60% were conducted in the USA); 1 study did not report country.

**Key elements of health coaching:** Patient-centeredness was reported in 42% of studies, patient-determined goals reported in 31.6%, and self-discovery process reported in 21%; 1 study did not report any of the key elements.

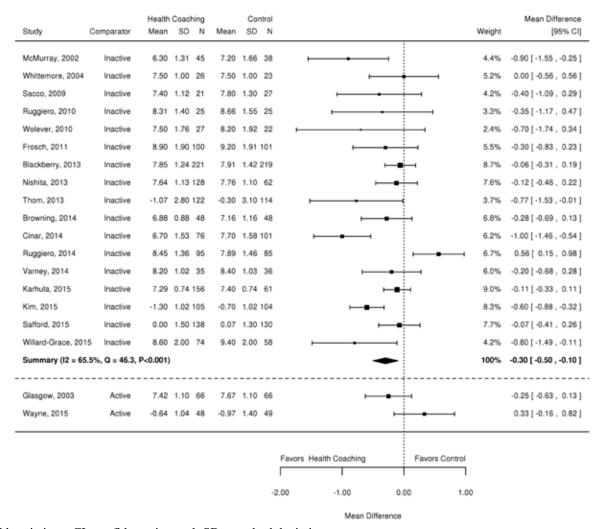
**Comparisons:** Most studies (n=18) compared health coaching with usual care, waitlist, or some other form of unenhanced control.

**Measurement of outcomes:** All studies reported change in HbA1c outcomes. **Risk of bias:** 1 study was rated as low ROB; 12 unclear ROB; and 7 high ROB.

Of the 20 trials, all but one<sup>41</sup> measured HbA1c as a continuous variable; this study categorized HbA1c as a dichotomous variable (in or out of control) and could not be included in the meta-analysis. We stratified results by comparator type (inactive vs active) and present stratified and overall pooled estimates. An inactive comparator group was used in 17 trials; 1 trial was rated as low ROB,<sup>24</sup> 12 as unclear ROB,<sup>21,27,28,33,39,40,44,45,49,57,59,61</sup> and 7 as high ROB.<sup>20,30,34,41,46,55,58</sup> An active comparator group (such as another type of health coaching) was used in only 2 studies.<sup>30,57</sup> Thus, we could not produce a pooled estimate. Figure 2 shows the forest plot examining the effect of health coaching on HbA1c. The pooled estimate indicated a statistically significant effect for health coaching interventions on HbA1c when compared with an inactive comparator ( $\Delta$ A1c -0.30; 95% CI -0.50 to -0.10). This summary estimate had high heterogeneity ( $I^2$ =65.5%).



Figure 2. Effect of Health Coaching on HbA1c



Abbreviations: CI=confidence interval; SD=standard deviation

We identified 3 additional trials that examined the effect of health coaching on HbA1c. <sup>30,41,57</sup> Results were null in all 3 studies. In contrast to the pooled analysis, 1 study <sup>41</sup> compared a phone-based coaching intervention with usual care and found no significant difference in proportion of patients achieving A1c <7.0%. The other 2 studies compared health coaching with a more robust, active comparator. One trial <sup>57</sup> compared a health coaching intervention with a more intensive coaching intervention that involved real-time, on-demand access to the coach through a phone application; this study showed no significant difference between the 2 coaching interventions. Another trial <sup>30</sup> compared a tailored self-management coaching intervention to a peer support group and found no difference between these 2 active arms.

#### Effects on Cardiovascular Health

Six of the eligible RCTs examined the impact of health coaching on one or more cardiovascular outcomes across these chronic disease conditions: cardiovascular disease, hypertension, coronary artery disease or congestive heart failure, or a mixture of conditions. <sup>16,41,51-53,59</sup> Findings are grouped by systolic blood pressure and cholesterol. Table 6 summarizes key elements of the 6 studies.

#### Table 6. Evidence Profile of Studies Reporting Change in Cardiovascular Health

Number of trials: 6 published 2002-2015.

Number of participants: 4167 total (average/trial=595, range 245 to 1835).

**Setting:** Most participants were recruited from primary care (n=4), with the remaining (n=2) from a specialist cardiology clinic.

**Countries:** 3 countries were represented (Australia, Finland, and USA; 50% were conducted in the USA).

**Key elements of health coaching:** Patient-centeredness was reported in 44.4% of studies; self-discovery process reported in 44.4%, and patient-determined goals reported in 31.6%; 11.1% did not report any key element.

**Comparisons:** All 6 studies compared health coaching with usual care.

**Measurement of outcomes:** Most studies (n=5) reported systolic blood pressure; 1 study reported LDL cholesterol, 1 reported total cholesterol, and 1 reported Framingham risk score.

Risk of bias: 3 studies were rated as low ROB and 3 as unclear ROB.

#### Systolic Blood Pressure

Five of the 6 trials examined the effect of health coaching on systolic blood pressure. <sup>16,41,51,53,59</sup> One trial, rated as low ROB, <sup>16</sup> targeted patients with hypertension and compared the effects of small-group, in-person health coaching focused on dietary behavior change with a physician-focused quality improvement intervention. This study found that patients who received health coaching had a 2.6mmHg drop in systolic blood pressure (95% CI -4.4 to -0.7; p=0.01) at 6 months, although this change did not persist at 18 months. Another trial rated as low ROB<sup>51</sup> compared a mixed intervention of phone and in-person individual counseling with usual care. This study found that at 6 months, patients who completed the coaching intervention had a 6.4-mmHg reduction in systolic blood pressure compared with the control group. Three additional trials were of mixed quality (high or unclear ROB) and concluded that health coaching was not associated with a significant reduction in blood pressure. <sup>41,53,59</sup> Two of these focused on patients with heart disease <sup>41,53</sup> while the third focused on a mixed population of participants with uncontrolled diabetes, hypertension, or hyperlipidemia. <sup>59</sup>

#### Cholesterol

Four of the 6 trials examined the effects of health coaching on cholesterol (total cholesterol or LDL). A1,52,53,59 Of these, 1 was rated as low ROB, 2 as unclear ROB, 2 and 1 as high ROB. These studies produced mixed findings, with most reporting no statistical or clinically significant effects of health coaching on cholesterol. The trial rated as low ROB recruited patients immediately following revascularization procedures and compared personalized phone-based health coaching to usual care for changes in cholesterol. This study found that at the 6-month follow-up, patients who received health coaching had a 14mg/dL (0.36mmol/L) greater drop in mean total cholesterol level compared with those who received usual care (0.328mmol/L to 0.163mmol/L; p <0.02).

One trial rated as unclear ROB<sup>59</sup> examined the proportion of patients meeting cholesterol-reduction goals in a health coaching intervention for a mixed population. No significant difference was found between the health coaching (43%) and the usual care groups (37%) (95%)





CI -4 to 25, p=0.15). The second trial rated as unclear ROB<sup>52</sup> found a positive effect of health coaching on mean cholesterol level in the health coaching group compared with control (5.0mmol/L vs 5.54mmol/L; p<0.0001) as well as LDL cholesterol (3.11 vs 3.57; p=0.0004); no positive effect was found on HDL cholesterol. The trial rated as high ROB<sup>41</sup> compared phone-based health coaching with usual care in patients with coronary artery disease or congestive heart failure. This study found that cholesterol-reduction goals were achieved more often in the health coaching arm compared with the control arm, yet there were no significant reductions in cholesterol endpoints between the 2 groups.

#### Effects on Functional Status

Two of the eligible RCTs examined the impact of health coaching interventions on functional status compared with inactive controls. <sup>35,47</sup> One study was rated as unclear ROB<sup>35</sup> and one as high ROB<sup>47</sup>; results were mixed. Both coaching interventions sought to increase physical activity in individuals with physically disabling conditions, rheumatoid arthritis, <sup>35</sup> and multiple sclerosis, 47 and also assessed the impact of health coaching on functional status. The trial with unclear ROB (n=78) investigated the effect of six 2-hour group sessions over 6 weeks, then monthly coaching calls for 1 year, by trained nurses or community health workers compared to an education control with one nurse-led group session in individuals with rheumatoid arthritis.<sup>35</sup> Functional status was measured using the 20-item disability scale of the Health Assessment Questionnaire. No differences were found between groups in functional status postintervention (Cohen's d=0.03) or at a 32-week follow-up (Cohen's d=0.04). The trial with high ROB (n=76) explored the impact of 15 one-on-one coaching sessions via Skype over 6 months compared to waitlist control in individuals with multiple sclerosis.<sup>47</sup> This trial used an objective measure, the 6-minute walk test, to assess changes in functional status. At the end of the 6-month intervention, the intervention group demonstrated improvements in self-reported physical activity and an increased 6-minute walk distance (partial- $\eta^2 = 0.07$ ) compared with the control group.

#### **Detailed Findings for Patient Health Behaviors (KQ 1b)**

In this section, we describe findings by effects on physical activity, weight management, diet, smoking, and medication adherence.

#### Effects on Physical Activity

Seventeen of the eligible RCTs examined the impact of health coaching on physical activity across these chronic disease conditions: type 2 diabetes (n=8), cancer (n=2), obesity (n=2), rheumatoid arthritis (n=2), systemic lupus erythematosus (n=1), multiple sclerosis (n=1), or a mixture of chronic diseases (n=1). <sup>20,21,25,26,29-32,35,43,45,47,48,54,55,58,61</sup> Table 7 summarizes key elements of the 17 studies.

#### Table 7. Evidence Profile of Studies Reporting Change in Physical Activity

Number of trials: 17 published 2003-2016.

Number of participants: 3119 total (average/trial=183, range 32 to 504).

**Setting:** Most participants were recruited from primary care (n=5) or specialty clinics (n=5), with a few studies recruiting from the community, university, registry, or a combination; only 1 study recruited from a VA clinic.

**Countries:** 4 countries were represented (Australia, the Netherlands, Sweden, and USA; 65% were conducted in the USA).





**Key elements of health coaching:** Patient-centeredness and patient-determined goals were equally prominent in the studies (70.5%), while self-discovery process was reported in 29%.

**Comparisons:** 4 studies had active comparators: 2 provided coaching via another mode; 1 provided all the same materials but was self-directed, and 1 provided an attention control around other aspects of the condition; the other 13 trials used usual care, education, or waitlist.

**Measurement of outcomes:** The primary physical activity outcome was self-reported in 16 studies using multiple questionnaires; 1 study used an objective measure in the form of a pedometer as the primary measurement; 1 study validated a self-report questionnaire with measured or imputed accelerometer results.

Risk of bias: 1 study was rated as low ROB, 7 as unclear ROB, and 9 as high ROB.

Two studies measured physical activity as a categorical variable and 15 measured the outcomes as a continuous variable. Of the 15 trials that were amenable to quantitative synthesis, however, physical activity was measured in 2 conceptually distinct ways. Thus we separated the 15 trials into 2 groups: (1) 10 studies that measured physical activity as a continuous variable using metrics such as steps/day or minutes/day or week, which hereafter is called "physical activity change" 29-32,35,43,47,48,55,58 and (2) 5 studies that measured physical activity as a continuous variable above some cut-off threshold (*eg*, 30 minutes of activity/day), which hereafter is called "physical activity threshold." These 2 approaches to the measurement of physical activity were considered different enough to require separate meta-analyses. In addition, within each of these broad categories, there was substantial variability in the mode and metrics of scales used to measure physical activity. Therefore, all summary estimates were calculated as standardized mean differences (SMDs). Last, we provide a qualitative description of findings for the 2 trials that could not be pooled with the other studies.

#### Physical Activity Change

The 10 trials evaluated in the physical activity change meta-analysis comprised 6 inactive comparators \$^{31,32,35,47,55,58}\$ and 4 active comparators. \$^{29,30,43,48}\$ The 6 trials in the inactive group contained 1215 participants and were judged either unclear (n=3) or high (n=3) ROB. The 4 trials in the active group contained 940 participants and were all judged as high ROB. Figure 3 shows the forest plot examining the effect of health coaching on physical activity change stratified by inactive and active comparator subgroups. When compared with inactive controls, the pooled estimate demonstrated a small positive effect of health coaching interventions on physical activity change that was statistically significant (n=6; SMD 0.29; 95% CI 0.15 to 0.43). This summary estimate exhibited no heterogeneity (I²'d=0.0%). This effect disappeared when health coaching was compared with active controls (n=4; SMD 0.17; 95% CI -0.32 to 0.67). This summary estimate showed moderate heterogeneity (I²'d=53.2%).

Health Coaching Control Standardized Mean Difference Study SD N Comparator SD N Mean Weight 195% CII Mean Whittmore, 2004 399.00 359.00 26 301.00 299.00 23 0.29 [ -0.27 , 0.85 ] Holland, 2005 -16.20 101.30 249 46.2% 0.35 [ 0.18, 0.53] Inactive 18.70 96.80 255 Inactive 0.20 [ -0.02 , 0.42 ] Sandroff, 2014 0.54 [ 0.08 , 1.00 ] Inactive 20.70 37 17.00 39 Varney, 2014 115.00 123.76 35 119.00 123.98 36 -0.03 [ -0.50 , 0.43 ] Knittle, 2015 Inactive 303.00 294.00 36 212.00 285.00 31 0.31 [ -0.17 , 0.79 ] Summary (I2 = 0.0%, Q = 4.1, P=0.53) 0.29 [ 0.15 , 0.43 ] Glasgow, 2003 Active 30.90 23.00 66 32.10 22.90 66 29.2% -0.05[-0.39, 0.29] Sherwood, 2010 0.40 [ -0.28 , 1.08 ] Active 564.30 1132.79 18 116.00 1068.00 16 13.2% Damschroder, 2014 Active 1019.00 4049.21 142 914.00 5610.60 137 37.2% 0.02[-0.21, 0.26] 0.63 [ 0.14 , 1.12 ] Pinto, 2015 54.60 81.60 36 13.40 35.20 31 20.3% 0.17 [ -0.32 , 0.67 ] Summary (I2 = 53.2%, Q = 6.4, P=0.093) 100% Favors Favors Health Coaching 1.00

Figure 3. Effect of Health Coaching on Physical Activity Change

Abbreviations: CI=confidence interval; SD=standard deviation; SMD=standardized mean difference

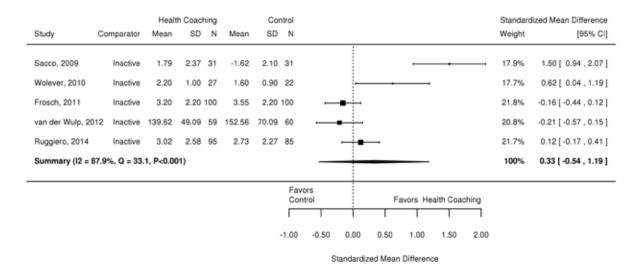
Three trials that examined the effect of health coaching on physical activity change had more arms than were included in the meta-analysis. <sup>29,30,48</sup> These were all conducted in the United States on populations with obesity <sup>29,48</sup> or diabetes. <sup>30</sup> All trials were judged as high ROB and had active control groups. The first study on obesity (n=481)<sup>29</sup> examined a second mode of coaching (via the phone) versus in-person group coaching or the VA's weight control program, MOVE!, over a year. The second study on obesity (n=63)<sup>48</sup> examined a second coaching duration length (10 weeks instead of 20 weeks) versus a self-directed control group, all using the same study materials with follow-up at 6 months. The study on diabetes (n=320)<sup>30</sup> examined a second mode of coaching (from a peer rather than a professional) versus self-directed access to all materials via the internet. However, none of these additional comparisons showed any statistically significant differences between groups, in keeping with the result of the meta-analysis for active comparators (Figure 3 above).

Standardized Mean Difference

#### Physical Activity Threshold

The 5 trials evaluated in the physical activity threshold meta-analysis all used inactive comparators. <sup>20,21,34,45,54,61</sup> These trials contained 711 participants and were judged either unclear (n=3) or high (n=2) ROB. Figure 4 shows the forest plot examining the effect of health coaching on physical activity threshold. The pooled estimate demonstrated a small positive effect of health coaching interventions on physical activity threshold when compared with inactive controls, but it was not statistically significant (n=5; SMD 0.33; 95% CI -0.54 to 1.19). This summary estimate exhibited high heterogeneity (I<sup>2</sup>'d=87.9%).

Figure 4. Effect of Health Coaching on Physical Activity Threshold



Abbreviations: CI=confidence interval; SMD=standardized mean difference

#### Qualitative Findings for Physical Activity

Two of the 17 RCTs examining the effect of health coaching on physical activity could not be pooled with the other studies. <sup>25,26</sup> One was rated as low ROB<sup>25</sup> and the other as high ROB. <sup>26</sup> These trials were conducted in populations with rheumatoid arthritis (n=228)<sup>26</sup> or systemic lupus erythematosus (n=32)<sup>25</sup> and were majority or entirely female. Both trials examined categorical variables: attainment of a "healthy" goal (moderate to high intensity physical activity 4 times/week) or a specific frequency category for high or moderate-to-high intensity physical activity versus usual care. Both interventions lasted 1 year. One intervention<sup>26</sup> was monthly coaching by phone. The other<sup>25</sup> consisted of coaching every 6 weeks for 3 months decreasing over time. In addition, participants received supervised exercise, a heart rate monitor and a physical activity diary. Despite differences in study size, quality, and intervention intensity, neither study found any significant differences in physical activity between intervention and control groups. One possible reason might be the high exercise intensity level set for reaching the goal or moving between categories, which would be difficult to attain for these populations.

#### Effects on Weight Management

Twenty of the eligible RCTs examined the impact of health coaching on weight as measured in changes in pounds or kilograms (n=12), body mass index (BMI) (n=16), or both pounds/kilograms and BMI (n=8). 19,21,23,24,27,29,31-33,36,37,40,46,48,49,53,55-58 These RCTs examined the impact of health coaching on weight management across the following chronic disease conditions: type 2 diabetes (n=9); obesity (n=6); metabolic syndrome (n=1); colorectal cancer (n=1); cardiovascular disease (n=1); mixed chronic disease conditions (n=1); and one study that contained 2 study subgroups of type 2 diabetes and cardiovascular disease. Table 8 summarizes key elements of the 20 studies.

#### **Table 8. Evidence Profile of Studies Reporting Weight Management Outcomes**

Number of trials: 20 published 2003-2015.

Number of participants: 5640 total (average/trial=282, range 45 to 792).

**Setting:** Most participants were recruited from primary care (n=8) or community clinics (n=4); others from a cancer registry (n=2), specialty clinic (n=2), general outpatient clinic (n=1), community/university (n=1), community/work place (n=1), university only (n=1), and VA setting (n=1).

**Countries:** 6 countries were represented (Australia, Canada, China, Finland, Germany, USA; 55% were conducted in the USA).

**Key elements of health coaching:** Patient-centeredness was reported in 70% studies; self-discovery process and patient-determined goals were equally prominent (50% and 55% of the studies, respectively); 20% of studies provided no information on any key elements.

**Comparisons:** 6 studies compared health coaching with active comparators; the remaining 14 used usual care, treatment as usual, education, or waitlist.

**Measurement of outcomes:** Measure of weight management/change in pounds/kilograms was reported in 12 studies, BMI was reported in 16 studies, and 8 studies reported both.

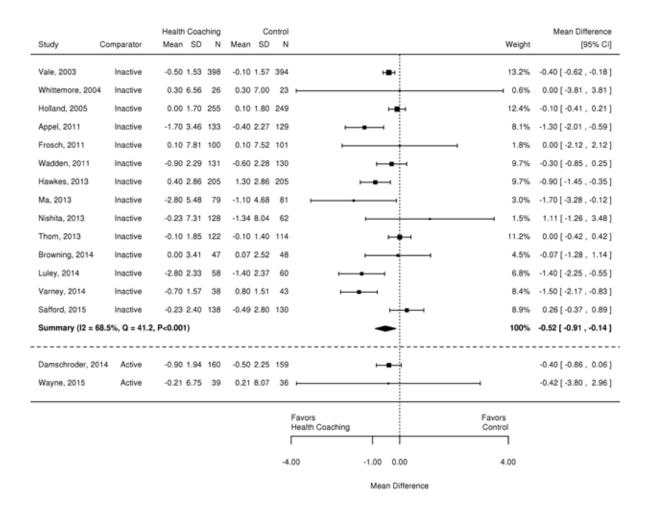
Risk of bias: 3 studies were rated as low ROB, 10 as unclear ROB, and 7 as high ROB.

As change in BMI was the most common metric across the 20 studies, we conducted a quantitative synthesis by this outcome. Sixteen of the 20 trials reported change in BMI and were amenable to quantitative synthesis. We stratified results by comparator type (inactive vs active) and present stratified and overall pooled estimates when feasible. Last, we provide a qualitative synthesis of findings for the 4 trials that reported outcomes as change in kilograms or pounds only and could not be pooled with the other studies.

The 16 trials that explored the impact of health coaching on BMI contained 4021 participants and were judged either low (n=2), unclear (n=9), or high (n=5) ROB. Figure 5 shows the forest plot examining the effect of health coaching on change in BMI. The pooled estimate demonstrated a positive effect of health coaching interventions when compared with inactive controls (n=14; MD -0.52; 95% CI -0.91 to -0.14). This summary estimate exhibited high heterogeneity (I²=68.5%).



Figure 5. Effect of Health Coaching on BMI



#### Qualitative Findings for BMI

Five trials that examined the effect of health coaching on BMI change had more coaching-related arms than were included in the meta-analysis (n=3<sup>23,29,56</sup>) or compared health coaching with more robust, active comparators (n=1<sup>57</sup>), and could not be included in the summary estimate with the inactive comparators. One 2-arm trial of unclear ROB<sup>57</sup> compared a health coaching intervention with a more intensive coaching intervention that involved real-time, on-demand access to the coach through a phone application for patients with diabetes; this study showed no significant difference between the 2 coaching interventions.

The other 3 remaining trials with more than 2 coaching-relevant arms were all conducted among populations with obesity. Results were mixed. The first 3-arm study<sup>23</sup> compared in-person coaching with phone-delivered coaching or usual care. In both coaching arms, the frequency of the interventions was the same (12 weekly coaching sessions followed by monthly coaching session for the duration of the 24-month intervention). Both coaching arms produced the same statistically significant reduction in BMI compared with usual care (1.7 vs 0.4 decrease in BMI; p-values not reported). This trial was rated as unclear ROB. Another study rated as unclear ROB<sup>56</sup> compared usual care with brief monthly lifestyle coaching with or without meal replacement or weight loss medications. (Figure 5 above displays the contrast between usual care and the brief lifestyle coaching without meal replacement condition.) There were no significant



differences between arms on change in BMI. Last, one 3-arm study at high ROB<sup>29</sup> examined a second mode of coaching (via the phone) versus in-person group coaching or the VA's MOVE! weight control program over a year among Veterans with obesity. Participants in all three groups achieved statistically significant reductions in BMI at 12 months. Group coaching outperformed both MOVE! and phone coaching, but the contrast with MOVE! was not statistically significant (Figure 5).

#### Qualitative Findings for Weight Management in Pounds or Kilograms Only

There were 4 studies conducted in North America, Scandinavia, or Australia that presented data on change in pounds/kilograms but not BMI. <sup>19,24,33,48</sup> These findings are synthesized qualitatively. All 4 health coaching interventions were delivered via telephone. Two studies were conducted in patients with obesity, one was conducted in patients with type 2 diabetes, and one study looked at the effect of the same intervention on 2 populations, one with type 2 diabetes and one with cardiovascular disease (CVD).

The 2 obesity studies had conflicting results: one study with high ROB<sup>48</sup> showed a positive effect of health coaching, while the other study with high ROB<sup>19</sup> showed a positive effect for the active control group. The latter study<sup>19</sup> assessed the effect of weekly health coaching sessions that emphasized motivational interviewing versus structured lifestyle change instruction over 12 weeks. The noncoaching lifestyle change arm decreased weight more (-3.5 kg vs -1.1 kg, p=0.01) at post-intervention than the coaching arm. However, there was a 73% dropout rate among these participants. The other study<sup>48</sup> assessed 3 groups, 2 of which received weekly phone calls from a coach, either 10 or 20 sessions, over 6 months. The control group received all of the materials—an instructional manual, a pedometer, and a log book for self-monitoring—but did not receive any personal contact. On average, the 20-call group lost twice as much weight as the self-directed group (-4.9 kg vs -2.3 kg), while the average weight loss of the intermediary 10-call group was -3.2 kg (p values not given).

Neither diabetes study, one with low ROB<sup>24</sup> and one with unclear ROB,<sup>33</sup> found positive effects on weight loss in kilograms for health coaching versus an inactive control. The latter study,<sup>33</sup> which also looked at CVD, did not find a positive effect of health coaching. The diabetes studies<sup>24,33</sup> had inactive, usual care control groups, used change in weight (kg) as a secondary outcome, and had completion rates over 90%. One study<sup>24</sup> was a cluster RCT (n=473 from 30 primary care practices, mean age 47 to 48, 30% women) that assessed the effect of 8 nurse-led, structured health coaching sessions via phone over 18 months. They found no significant difference in weight between groups (p=0.89); however, the median number of sessions received was only 3 (interquartile range, 1 to 5). The other study<sup>33</sup> used the same intervention on 2 populations, diabetes (n= 250, mean age 66 years, 49% women) and CVD (n=267, mean age 69 years, 44% women). The intervention consisted of a 30-minute phone call from a trained health coach every 4 to 6 weeks over 12 months. They found no significant difference in weight between groups in either population.



#### Effects on Diet

Eleven of the eligible RCTs examined the impact of health coaching on an outcome related to diet for these chronic disease conditions: type 2 diabetes (n=6), obesity (n=2), cancer (n=1), hypertension (n=1), and coronary heart disease (n=1). 16,19-21,29-31,45,53,54,58 Table 9 summarizes key elements of the 11 studies.

## Table 9. Evidence Profile of Studies Reporting Change in Diet

Number of trials: 11 published 2003-2014.

Number of participants: 3325 total (average/trial=302, range 45 to 792).

**Setting:** Most participants were recruited from primary care (n=6); other from community/university (n=1), cancer registry (n=1), cardiology clinic (n=1), outpatient diabetes education setting (n=1), and VA setting (n=1).

**Countries:** 4 countries were represented (Australia, Canada, Netherlands, and USA; 64% conducted in the USA).

**Key elements of health coaching:** Patient-determined goals and patient-centeredness were reported in 100% and 91% of the studies, respectively; self-discovery process was reported in 55%.

**Comparisons:** 3 studies had active comparators: 1 used the VA MOVE program, 1 used in-home training to use a website providing chronic disease education without addition support, 1 used scripted education-based phone lesson principles from the LEARN manual; 8 used inactive comparators described as enhanced treatment as usual, usual care, treatment as usual, or education alone.

**Measurement of outcomes:** 6 studies reported some type of adherence to diet measure, 5 studies reported fruit and/or vegetable intake, 3 reported the Summary of Diabetes Self-care Activities diet subscale, 6 reported some type of fat-intake change, 2 reported kcal or energy intake, and 1 reported on dietary fiber intake.

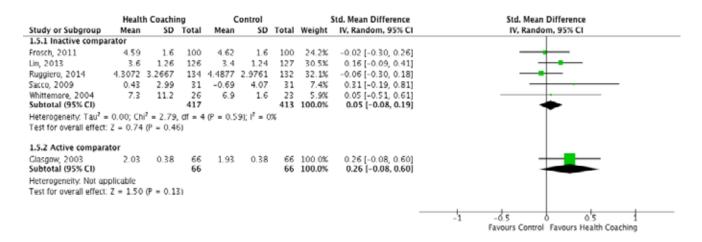
Risk of bias: 2 studies were rated as low ROB, 4 as unclear ROB, and 5 as high ROB.

Two studies were rated as low ROB, <sup>16,53</sup> 4 as unclear ROB, <sup>21,31,45,54</sup> and 5 as high ROB. <sup>19,20,29,30,58</sup> Of the 11 studies, which examined the outcome of diet as a continuous variable, 10 were amenable for quantitative synthesis. There was substantial variability in the mode and metrics of scales used to measure diet. Therefore, we conceptualized change in diet as one of the following 4 types of outcomes: (1) adherence to some sort of prespecified diet plan, <sup>16,20,21,30,45,58</sup> (2) change in dietary fat consumption, <sup>16,29-31,53,54</sup> (3) change in total calories, <sup>16,19</sup> or (4) change in fruit and vegetable consumption. <sup>16,19,20,29,31</sup> Due to the variability in measurement, all summary estimates were calculated as SMDs. We stratified results by comparator type (inactive vs active) and present stratified pooled estimates.

#### Adherence to a Prespecified Diet Plan

Figure 6 shows the forest plot of the meta-analysis examining the effect of health coaching on diet adherence stratified by inactive and active comparator subgroups. The pooled estimate for 5 studies indicated a nonsignificant effect for health coaching interventions on diet adherence when compared with an inactive comparator (SMD 0.05; 95% CI -0.08 to 0.19). This summary estimate did not exhibit heterogeneity ( $I^2$ =0%). Of the 5 studies using inactive comparators, 1 was rated as low ROB<sup>16</sup> 2 as unclear ROB,<sup>21,45</sup> and 2 as high ROB.<sup>20,58</sup>

Figure 6. Effect of Health Coaching on Adherence to a Prespecified Diet Plan



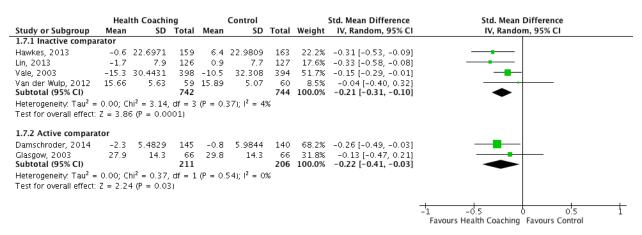
Abbreviations: CI=confidence interval: SD=standard deviation

In the one active comparison study in adults with type 2 diabetes,<sup>30</sup> participants were randomized to one of 3 groups: web-based information alone, or web-based information with either peer support or tailored self-management from a coach. There were no significant differences between those who received peer support compared with those who did not. There was a small positive effect (SMD 0.26; 95% CI -0.08 to 0.60) that was not statistically significant for health coaching in the form of tailored self-management when compared with an active comparator that did not include health coaching in the form of tailored self-management.

## Change in Dietary Fat Consumption

Figure 7 shows the forest plot of the meta-analysis examining the effect of health coaching on change in dietary fat intake stratified by inactive and active comparator subgroups. The pooled estimate indicated a small statistically significant pooled effect for health coaching to decrease dietary fat intake when compared to an inactive comparator (SMD -0.21; 95% CI -0.31 to -0.10). This summary estimate had low heterogeneity ( $I^2=4\%$ ). There was also a small pooled effect (SMD -0.22; 95% CI -0.41 to -0.03) that was statistically significant for health coaching to reduce dietary fat intake when compared with an active comparator. This summary estimate also had low heterogeneity ( $I^2=0\%$ ).

Figure 7. Effect of Health Coaching on Fat Consumption



Abbreviations: CI=confidence interval; SD=standard deviation; SMD=standardized mean difference

Two of the studies using active comparators had more than 2 arms.<sup>29,30</sup> As stated for diet adherence, one study<sup>30</sup> also examined the effect of peer support but did not find any effect on grams of daily fat intake. In the other,<sup>29</sup> coaching was delivered by phone as well as in a group setting compared with the intensive weight control program currently offered by the VA (MOVE!). The figure shows that group coaching decreased fat intake more than MOVE!. Phone coaching also decreased fat intake more than MOVE! at 12 months (MD -1.6gm vs -0.8gm), but this difference was not statistically significant between groups. The difference between the 2 types of coaching, phone (-1.6gm fat) and group (-2.3gm fat), also was not statistically significant. Both of these studies had relatively large sample sizes (n>300) and were rated as high ROB.

#### Change in Total Calories

Only 2 studies measured total energy or kilocalorie intake; we summarize them qualitatively. <sup>16,19</sup> The study rated as high ROB<sup>19</sup> had 45 participants with obesity and compared phone coaching with a certified health coach to a scripted phone education lesson based on the LEARN manual, both provided once/week for 12 weeks. Diet was measured via a 24-hour recall that was reviewed with a staff member at 5 time points: baseline, 6 weeks, 12 weeks (end of treatment) and 3 and 6 months post-treatment. There was a significant difference (p<.05, r=0.32) between groups at 12 weeks (coaching mean: -626.8kcal, SE=167.4 vs LEARN mean: -105.5kcal, SE=180.3). Both groups maintained reduced caloric intake at 3 and 6 months post-treatment, but differences between groups were no longer significant. The study rated as low ROB<sup>16</sup> had a 2x2 factorial design study with 574 hypertensive participants and assessed the separate and combined influences of a physician training intervention and a patient intervention with lifestyle coaching over 6 months. Both groups that contained coaching elements decreased daily caloric intake more than the groups that did not contain coaching at both 6 (250-287kcal vs 72-171kcal, p<0.05) and 18 months (159-261kcal vs 73-119kcal), but was no longer significant at 18 months. Both of these studies indicate that coaching has a positive effect on total calorie reduction.

## Change in Fruit and Vegetable Consumption

Five studies examined the outcome of fruit and vegetable consumption: 3 used an inactive comparator <sup>16,20,31</sup> and 2 used an active comparator. <sup>19,29</sup> However, measurement varied

considerably between studies and meta-analysis could not be performed. We summarize these qualitatively.

The 3 studies with inactive comparators were all moderately large (n=270 to 574) but varied on population, how fruit and vegetable consumption was measured, and quality. A study rated as unclear ROB<sup>31</sup> examined 410 colorectal cancer patients using a cancer-specific food frequency questionnaire that asked about fruit and vegetable intake separately. There were no significant differences at 6 or 12 months in fruit intake between the phone coaching intervention and usual care. However, at 6 months patients in the coaching group ate 0.4 more servings of vegetables per day (p=0.001) than usual care. This difference was not maintained at 12 months.

A study rated as high ROB<sup>20</sup> examined 270 patients with diabetes who were either Hispanic or African American. The study compared culturally tailored self-care coaching delivered by medical assistants over 6 months to enhanced treatment as usual. They used the 5-item diet subscale of the Summary of Diabetes Self-care Activities, which does not isolate fruit and/or vegetable consumption. There were no significant differences between groups at either time point. The last study, rated as low ROB,<sup>16</sup> examined 574 patients with hypertension in a nested 2x2 design over 18 months: physician intervention (MD-I) or control (MD-C) and patient intervention (PT-I) (which included lifestyle coaching) or control (PT-C). Intake was measured by the Block Food Frequency Questionnaire. At 6 months, both MD-I and PT-I showed significant increased fruit and fruit juice consumption over control groups (p<0.05 and p<0.001, respectively). A significant difference was maintained at 18 months in the PT-I group but not the MD-I group.

The 2 studies with active comparators were both rated as high ROB. <sup>19,29</sup> The first was a 3-arm study<sup>29</sup> that used a food frequency questionnaire to measure diet. It is described under fat intake. The other study<sup>19</sup> used 24-hour recalls to measure diet. It is described under calorie intake (above). Neither study found any difference between groups in fruit and vegetable consumption.

# Effects on Smoking

Two of the eligible RCTs examined the impact of health coaching on smoking behavior. <sup>31,53</sup> Neither trial found an effect of health coaching on smoking behavior. However, neither trial was designed to address smoking behavior solely, targeting multiple health behaviors. One trial (n=792) rated as low ROB investigated a phone-based coaching program compared to usual care in individuals with coronary heart disease. <sup>53</sup> Participants received five 20- to 30-minute coaching calls delivered by a nurse or dietician over the course of 6 months. At 6 months, there was no difference between groups in self-reported rates of smoking cessation.

The other trial rated as unclear ROB investigated the effect of health coaching on multiple health behaviors among 410 individuals with colorectal cancer. This study compared an 11-session, 5-week phone-based coaching program with enhanced usual care. Sessions were delivered by nurses, behavioral specialists, or health educators and lasted an average of 31.5 minutes. Individuals in this trial reported a low rate of current smoking at baseline (3.9% in health coaching vs 4.3% in usual care), limiting the trial's ability to detect changes in smoking behavior over time. There were no differences between groups in self-reported current smoking at 6 months (the predetermined secondary outcome time point; 2.0% in health coaching vs 4.2% in usual care); or at a 12-month follow-up (1.0% in health coaching vs 5.3% in usual care).



#### Effects on Medication Adherence

Three of the eligible RCTs examined the impact of health coaching on medication adherence outcomes in patients with diabetes. <sup>21,59,61</sup> All 3 studies were rated as unclear ROB and used weak controls consisting of usual care. One study<sup>59</sup> found that health coaching was associated with a significant improvement in medication adherence, but 2 studies<sup>21,61</sup> did not find a positive effect on medication adherence.

The first study compared an in-person individual health coaching intervention with usual care. This study evaluated medication adherence based on patient self-report in which the mean number of days of adherence across all medications was calculated. Health coaching had a positive effect on medication adherence with participants in the intervention group reported 1.08 more days of medication adherence compared to usual care (p<0.001). The second study evaluated a phone-based coaching intervention compared with a standard educational brochure. This study operationalized medication adherence as the number of the past seven days the patient took all of prescription medications prescribed by his or her doctor. While participants in the health coaching group reported improved medication adherence, these results were not statistically significantly different from the control condition. The third study compared a motivational interviewing and mindfulness-based phone intervention with usual care. There was a significant reduction in barriers to medication adherence, as measured by the Morisky Adherence Scale, within the health coaching group (Z -2.862; p=0.004), but there was no significant time-by-group interaction.

# **Detailed Findings for Self-efficacy (KQ 1c)**

Eight of the eligible RCTs examined the impact of health coaching interventions on self-efficacy outcomes for these chronic disease conditions: type 2 diabetes (n=6), obesity (n=1), and arthritis (n=1). 22,24,34,35,45,54,62,63 Table 10 summarizes key elements of the 8 studies.

# Table 10. Evidence Profile of Studies Reporting Change in Self-efficacy

Number of trials: 8 published 2009-2015.

Number of participants: 1469 total (average/trial=184, range 22 to 473).

**Setting:** Most participants were recruited from primary care (n=4) or community clinics (n=4); 1 study recruited from a specialty rheumatology clinic.

**Countries:** 3 countries were represented (Australia, the Netherlands, USA; 62.5% were conducted in the USA).

**Key elements of health coaching:** Patient-centeredness and self-discovery process were equally prominent (75% of studies), and patient-determined goals were reported in 87.5% of studies.

**Comparisons:** 1 study had an active comparator (an equal number of individual meetings with a fitness specialist); the other 7 trials used usual care, treatment as usual, waitlist, or education.

**Measurement of outcomes:** Self-efficacy was reported using 7 different questionnaires within the 8 trials: 2 used the Diabetes Empowerment Scale; other scales were Stanford Chronic Disease Self-efficacy, Bandura Self-efficacy, Diabetes Self-efficacy, Diabetes Management Self-efficacy, Exercise Self-efficacy scales, and the Multidimensional Diabetes Questionnaire (self-efficacy subscale).

Risk of bias: 1 study was rated as low ROB, 5 as unclear ROB, and 2 as high ROB.

All 8 studies examined the impact of health coaching on self-efficacy using questionnaires with continuous scales and were therefore amenable for quantitative synthesis. However, there was substantial variability in the questionnaires used to measure self-efficacy, so all summary estimates were calculated as SMDs. We stratified results by comparator type (inactive vs active) and present stratified and overall pooled estimates when feasible.

The 8 trials used in the self-efficacy meta-analysis comprised 7 inactive comparators <sup>24</sup>,34,35,40,45,54,62 and one active comparator. <sup>22</sup> Figure 8 shows the forest plot examining the effect of health coaching on self-efficacy stratified by inactive and active comparator subgroups. The 7 trials with inactive comparators contained 1,196 participants and were rated as unclear ROB (n=5), high ROB (n=1), or low (n=1) ROB. When compared with inactive controls (usual care, n=5; waitlist, n=1; education only, n=1), the pooled estimate demonstrated a small-to-moderate positive effect of health coaching interventions on self-efficacy that was statistically significant (SMD 0.41; 95% CI 0.21 to 0.62) with moderate heterogeneity (*I*<sup>2</sup>=52.2%).

The study with an active comparator<sup>22</sup> had 137 participants and was rated as high ROB. This study compared 2 contact-equivalent conditions of 6 monthly, 1-hour individual meetings with a YMCA "Coach Approach-trained" wellness specialist compared to 6 sessions with a standard trained fitness specialist. This study demonstrated a moderate positive effect of health coaching on self-efficacy that was statistically significant (SMD 0.58; 95% CI 0.27 to 0.89).

Health Coaching Control Standardized Mean Difference Study Comparator Mean SD Mean SD [95% CI] Sacco, 2009 Inactive 422.97 176.40 31 352.42 163.48 9.2% 0.41 [ -0.09 , 0.91 ] Van der Wulp, 2012 74.80 11.67 13.8% 0.21 [ -0.15 , 0.57 ] Inactive 15.86 Blackberry, 2013 81.23 10.96 175 21.4% 0.11 [-0.09, 0.32] Inactive 79.94 11.46 194 Nishita, 2013 Inactive 4.19 0.68 128 3.84 0.63 16.1% 0.53 [ 0.22, 0.83] Young, 2014 0.53 [ 0.13, 0.93] 4.03 0.60 12.4% Inactive 3.64 0.84 Kim. 2015 0.60 [ 0.32 , 0.88 ] Inactive 9.50 12.30 105 1.80 13.26 17.6% Knittle, 2015 Inactive 0.68 [ 0.19 , 1.18 ] 95.80 27.49 27.49 Summary (I2 = 52.2%, Q = 12.6, P=0.051) 100% 0.41 [ 0.21 , 0.62 ] 0.58 [ 0.27, 0.89] Annesi, 2011 Active Favors Favors Health Coaching Control 0.00 1.00 1.50 -0.500.50

Standardized Mean Difference

Figure 8. Effect of Health Coaching on Self-efficacy

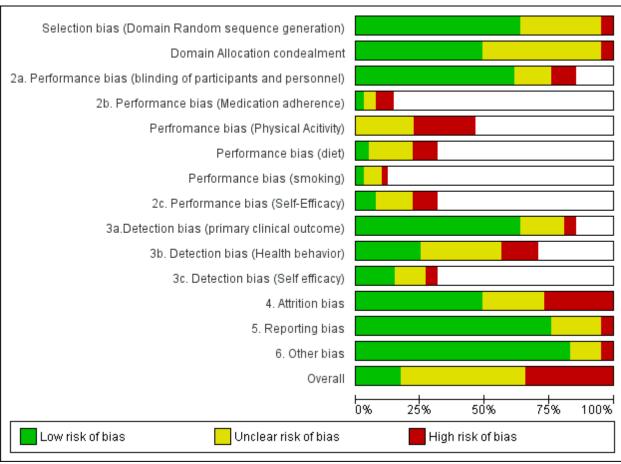
Abbreviations: CI=confidence interval; SD=standard deviation

## Quality of Evidence for KQ 1

#### Risk of Bias

Figure 9 presents a summary of the evaluation of the ROB, which shows a graph with review authors' judgments about each ROB item presented as percentages across all included studies. The white sections of the bars indicate the trials that did not measure a specific outcome. Appendix C describes the quality assessment criteria and presents a table of quality assessment responses for the 41 studies.

Figure 9. Risk of Bias Grapha



<sup>&</sup>lt;sup>a</sup> For the overall score, low ROB required random sequencing, allocation concealment, and blinding in order to be scored low risk with no other important concerns; unclear ROB was assigned if 1 or 2 domains were scored not clear or not done; high ROB was assigned if >2 domains were scored not clear or not done.

#### Selection Bias

#### Random Sequence Generation

Almost all included studies (95%) described treatment allocation as random. However, 13 (33%) of these 39 studies did not give the methods used to generate the random sequence and were thus judged as unclear ROB. Two studies were judged as high ROB because they did not address randomization at all.

#### Allocation Concealment

In 20 of the 41 trials (49%), methods for allocation concealment were described in sufficient detail to determine whether the intervention allocation could have been foreseen in advance of or during enrollment, resulting in a judgment of low ROB. In many trials (18 of 41 [44%]), there was an unclear ROB due to inadequate detail about allocation concealment provided by authors. The remaining 3 trials<sup>26,34,48</sup> (7%) were judged as high ROB because they either stated a procedure that could have caused allocation to become unblinded or they did not state whether the trial was randomized at all.

#### Performance Bias

For the outcome of clinical indicators (*eg*, A1c or blood pressure), which was measured in 33 (80%) studies, risk of bias was low in most studies (73%) as a result of adequate reporting of blinding or incomplete blinding that review authors judged was not likely to be a significant source of bias. In 6 of 33 trials (18%), there was an unclear ROB due to inadequate information regarding blinding. Three (9%) studies were judged as high ROB due to lack of blinding.

For the outcome of physical activity, which was measured in 17 (41%) studies, the blinding of participants and personnel was highly variable. Of the 17 trials measuring physical activity as an outcome, none were judged as low ROB. Eight trials (47%) were judged as unclear ROB due to inadequate information regarding blinding. Nine studies were judged as high ROB due to lack of blinding or incomplete blinding that review authors judged to be a potential source of bias.

Similar to physical activity, for diet outcomes, which were measured in 10 (24%) studies, the blinding of participants and personnel was highly variable. Of the 10 trials measuring diet as an outcome, only 2 (20%) were judged as low ROB as a result of adequate reporting of blinding. In 5 trials (50%), there was unclear ROB due to inadequate information regarding blinding. Three studies (30%) were judged as high ROB due to lack of blinding or incomplete blinding that review authors judged to be a potential source of bias.

The 3 other outcomes were measured in fewer than 10 studies. For self-efficacy (n=8, 19.5%), only one of the 8 studies (12.5%) was judged as low ROB as a result of adequate reporting of blinding. Four studies (50%) were judged as unclear ROB due to inadequate reporting, and 3 studies (37.5%) were judged as high ROB due to lack of blinding. For medication adherence (n=3, 7%), none were judged as low ROB. One was judged as unclear ROB due to inadequate information and the other 2 were judged as high ROB due to lack of blinding. Only 2 studies (5%) examined the outcome of smoking. One was judged as low ROB and the other was judged as unclear ROB.

#### **Detection Bias**

For the outcomes that were clinical variables (*eg*, HbA1c, BMI, blood pressure), measured in 33 of the 41 trials (80.5%), there was sufficient information provided by the authors regarding blinding of the outcome assessment in 25 of the 33 trials (76%) to be judged as low ROB. In the remaining 8 trials, 7 (21%) gave insufficient information regarding outcome blinding assessment, resulting in a judgment of unclear ROB, while 1 (3%) gave no information in regard to blinding and so was judged as high ROB.



For the outcomes that were health behaviors (*ie*, physical activity, diet, smoking, and medication adherence), measured in 22 of the 41 trials, 7 (32%) gave sufficient information provided by the study authors about blinding of outcome assessments to be judged as low ROB. Nine trials (41%) gave insufficient information regarding outcome blinding assessment and thus were judged as unclear ROB. Six trials (27%) were judged as high ROB due to lack of blinding.

Self-efficacy was measured in 8 trials, of which 3 (37.5%) gave sufficient information from the authors about blinding of the outcome assessment to be judged as low ROB. Four trials (50%) provided inadequate information about outcome blinding and so were judged as unclear ROB. One trial was judged as high ROB due to lack of blinding.

#### **Attrition Bias**

All trials reported the numbers randomized to each group. Approximately half the trials (20 of 41 [49%]) reported complete outcome data that included information on attrition, reasons for attrition or exclusion, and how missing data was handled in the analysis. The other 21 trials were judged as unclear ROB (n=10, 24%) or high ROB (n=11, 27%) because the dropout rate was too high, they did not disclose the reason for attrition/exclusion in sufficient detail, or they did not account for missing data in the analysis.

# Reporting Bias

The majority of trials (32 of 41 [76%]) reported details of the measured outcomes sufficient to be judged as low ROB. Seven trials (17%) did not give sufficient information on the outcomes and were therefore judged as unclear ROB. Two trials (5%) did not report at all on at least one of the outcomes proposed in the methods and were therefore judged as high ROB for selective outcome reporting.

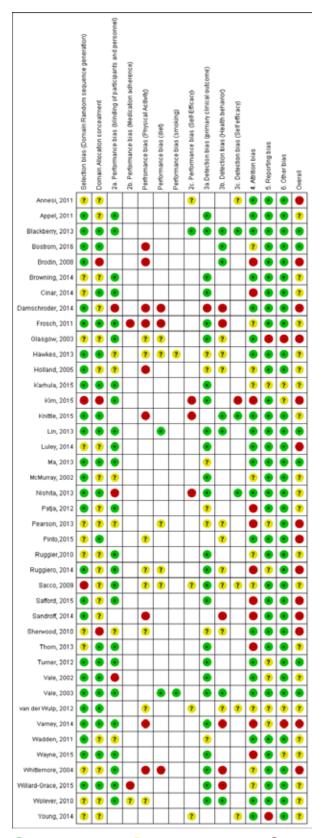
#### Other Bias

The majority of trials (35 of 41 [85%]) provided sufficient details not to raise concerns about bias of a nature not covered within the other domains mentioned. Four trials did not provide sufficient methodological detail and were thus judged as unclear ROB, whereas 2 trials (5%) were judged as high ROB stemming from between-group imbalances present at baseline even though randomized and not controlled in the analysis.

#### Overall Risk of Bias

Overall ROB was assessed for each included study (Figure 10). Almost half the studies (20 of 41 [49%]) were judged as unclear ROB, 15 (36.5%) as high ROB, and only 6 (14.5%) as low ROB.

Figure 10. Risk of Bias Summary: Review Authors' Judgments About Risk of Bias Items for Each Included Study<sup>a</sup>



 $\bullet$  = low risk of bias;  $\circ$  = unclear risk of bias;  $\bullet$  = high risk of bias

# **KEY QUESTION 2: Among adults, does the impact of health coaching vary by**

- a. Characteristics of the population (eg, type of chronic medical illnesses)
- b. Dose of the intervention (eg, number and frequency of sessions, minutes of contact)
- c. Mode of delivery (eg, individual visits vs group visits, face-to-face vs telephone)
- d. Types of individuals conducting coaching interventions (eg, peers, nurses, health educators, health coaches)
- e. Concordance with key elements of health coaching (*ie*, patient-centeredness, patient identification of goals, self-discovery process)

# **Key Points**

- We explored the variable impact of health coaching by multiple single factors that may contribute to heterogeneity (*ie*, recruited populations, intervention dose, mode of intervention delivery, coach type, concordance with key elements of health coaching).
   None of these individual factors was a robust predictor of heterogeneity. Yet some qualitative patterns of effects emerged.
  - Regardless of moderator category, most subgroups produced effects that were in the same direction but varied in magnitude, generally ranging from small to medium effect sizes in subgroups.
  - O While results on dose of intervention are inconclusive, there is some evidence that doses that were in the middle of the range in number of planned sessions may yield more benefit than those with smaller or larger numbers of planned sessions.
  - o Health coaching delivered either by telephone or in person yielded similar small to moderate positive effects across several outcomes. However, not all estimates were statistically significant.
  - O The majority of analyses identified no clear pattern of effect by type of individual conducting the coaching intervention. There is some limited evidence from studies that reported HbA1c and physical activity outcomes that use of behavioral healthcare providers may positively influence the effect of health coaching; however, this evidence is limited and inconsistent.
  - The intervention concordance score, a variable designed for this report to attempt to identify important elements of health coaching, does not appear to have any consistent effect.

For KQ 2, we present detailed findings exploring the variability of effects of health coaching by the 5 key moderators of interest. Studies that were amenable to meta-analysis were assessed to see if changes in outcomes varied by population characteristics (KQ 2a), intervention dose (*ie*,



number of planned sessions of health coaching) (KQ 2b), mode of coaching delivery (KQ 2c), type of individual providing the coaching (eg, healthcare provider, peer) (KQ 2d), and intervention concordance score (KQ 2e). When we had 3 or more studies in a category, we performed a meta-analysis. We use forest plots to visually inspect the data for patterns and synthesize findings qualitatively.

In keeping with the structure of KQ 1, we organize the findings in KQ 2 by the 3 types of outcomes—clinical health outcomes, patient health behaviors, and self-efficacy—and within those, we describe variations by the 5 key moderators of interest.

## **Detailed Findings for Clinical Health Outcomes**

In this section, we describe findings by effects on HbA1c, cardiovascular health (systolic blood pressure, cholesterol), and functional status.

#### Effects on HbA1c

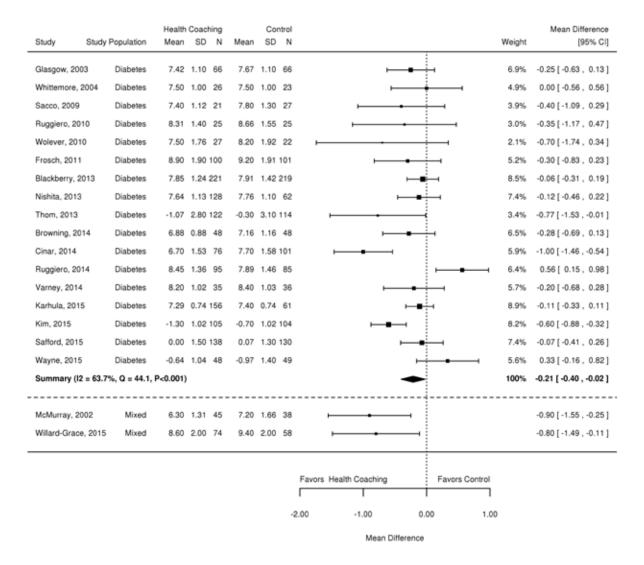
Twenty of the eligible RCTs examined the impact of health coaching on HbA1c. <sup>20,21,24,27,28,30,33,34,39-41,44-46,49,55,57-59,61</sup> Of these, 19 were amenable to meta-analysis and were examined for heterogeneity of effects by the key moderators of interest.

## Variation by Population Characteristics

Of the 20 trials, we had sufficient studies to pool effects for one population subgroup: those with diabetes. This subgroup had 17 studies. The other group comprised studies that recruited populations with a variety of chronic medical conditions and only contained 2 studies. Both subgroups displayed a similar direction of effect but the magnitude of the effect was different (Figure 11). Those recruited for diabetes had a smaller effect size (-0.21; 95% CI -0.40 to -0.02) compared to the rage of effect sizes for the studies comprised of mixed populations (range -0.90 to -0.80).



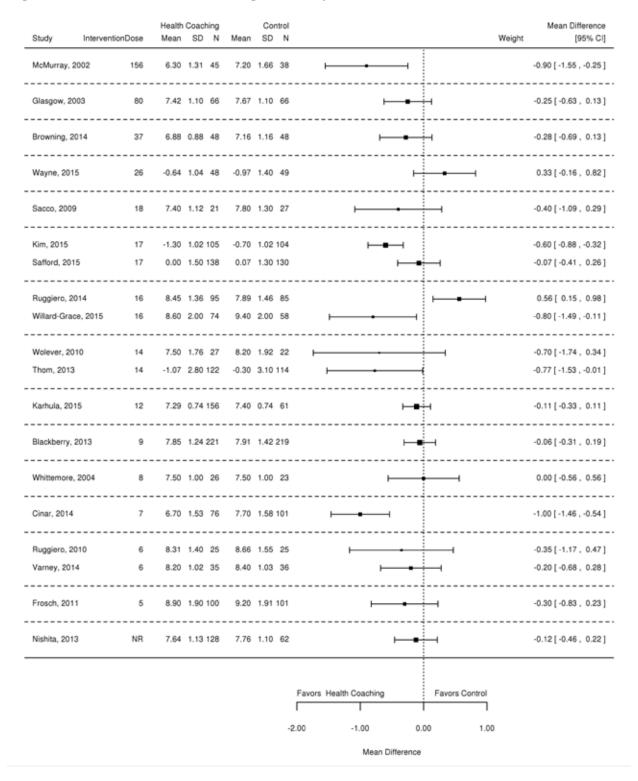
Figure 11. Effect of Health Coaching on A1c by Population Characteristics



#### Variation by Dose

Eighteen studies had enough information to determine the dose of the intervention measured as planned number of intervention contacts. The number of planned contacts ranged from 5 to 156, with a median of 15. Qualitatively, we did not see any evidence of a dose response number of session on the outcome of HbA1c (Figure 12).

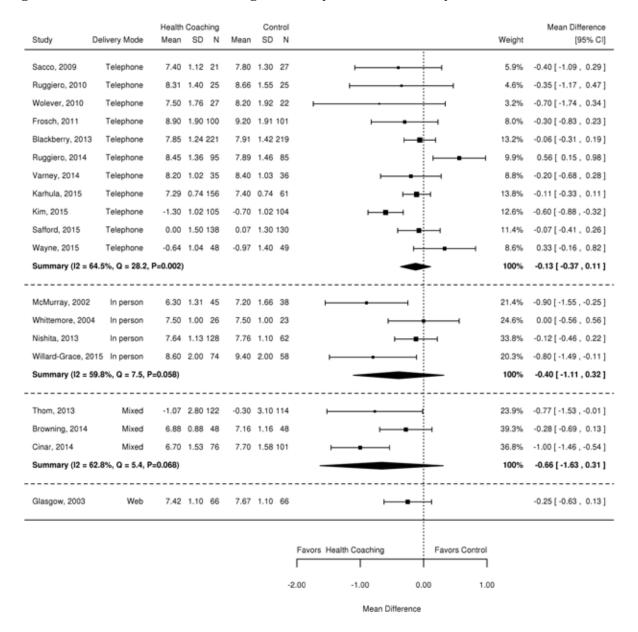
Figure 12. Effect of Health Coaching on A1c by Dose (Number of Planned Contacts)



## Variation by Mode

Studies generally delivered their coaching intervention by phone (n=11),<sup>20,21,24,33,34,44-46,55,57,61</sup> in person (n=4),<sup>39,40,58,59</sup> or with some mix of those 2 (n=3).<sup>27,28,49,52</sup> One study used a web-based coaching intervention.<sup>30</sup> Subgroups displayed a similar direction of effect, but the magnitude of the effect was slightly different. Studies that used a mix of phone and in-person sessions had a slightly greater impact, but all pooled subgroup effects were not statistically significant (Figure 13).

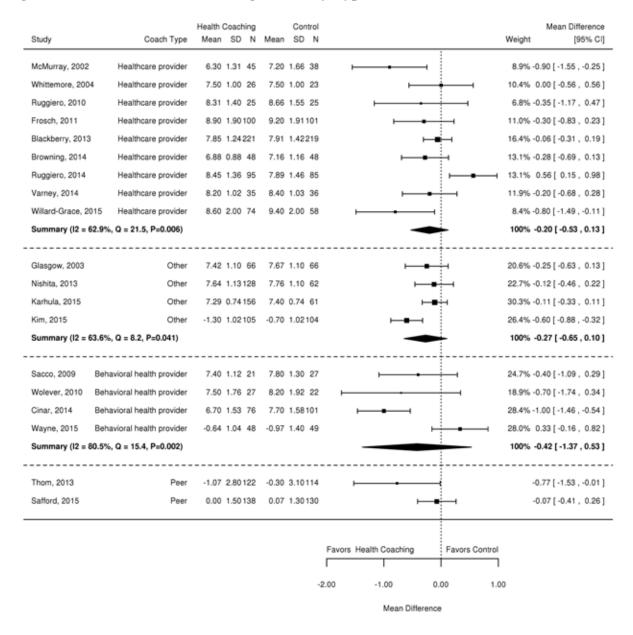
Figure 13. Effect of Health Coaching on A1c by Mode of Delivery



Variation by Types of Individuals Conducting Coaching Interventions

Studies used a wide variety of personnel in the health coaching role (Figure 14). Nine used a nurse or other licensed healthcare provider<sup>20,21,24,27,39,44,55,58,59</sup> as the coach. Four used a licensed behavioral provider, typically a psychologist or social worker.<sup>28,45,57,61</sup> Two used peer coaching,<sup>46,49</sup> and 4 used some other personnel as coaches (nurse or lay health worker at study discretion<sup>34</sup>; unspecified employees of the healthcare system<sup>33</sup>; professional life coaches<sup>40</sup>; masters'-level health science students<sup>30</sup>). Qualitatively, most coach types appeared roughly equally effective, with behavioral health providers having the largest pooled effects.

Figure 14. Effect of Health Coaching on A1c by Type of Coach



#### Variation by Concordance

An equal number of studies received concordance scores of 3 or the maximum, 4 (Figure 15). No clear pattern emerged when we conducted exploratory subgroup analysis by concordance score;



however, only the summary estimate for a concordance score of 4 was statistically significant and was similar in magnitude for the pooled estimate for the impact of health coaching compared to an inactive comparator in KQ 1 (-0.36 vs -0.30).

Figure 15. Effect of Health Coaching on A1c by Concordance

Study	Concordance Score	Health Coaching Mean SD N	Control Mean SD N			Mean Difference Weight [95% CI]
Wolever, 2010	4	7.50 1.76 27	8.20 1.92 22	-		5.0% -0.70 [ -1.74 , 0.34 ]
Frosch, 2011	4	8.90 1.90 100	9.20 1.91101	-	•	14.2% -0.30 [ -0.83 , 0.23 ]
Nishita, 2013	4	7.64 1.13128	7.76 1.10 62		<b>-</b>	22.5% -0.12 [ -0.46 , 0.22 ]
Kim, 2015	4	-1.30 1.02105	-0.70 1.02104	⊢-	⊣	25.9% -0.60 [ -0.88 , -0.32 ]
Safford, 2015	4	0.00 1.50138	0.07 1.30130		<b>⊢</b> •	22.6% -0.07 [ -0.41 , 0.26 ]
Willard-Grace, 2015	4	8.60 2.00 74	9.40 2.00 58	<del></del>	<b>-</b>	9.8% -0.80 [ -1.49 , -0.11 ]
Summary (I2 = 48.0%	6, Q = 9.6, P=0.087)			-	-	100%-0.36 [ -0.66 , -0.05 ]
Glasgow, 2003	3	7.42 1.10 66	7.67 1.10 66			19.6% -0.25 [ -0.63 , 0.13 ]
Whittemore, 2004	3	7.50 1.00 26	7.50 1.00 23	-		14.7% 0.00 [-0.56 , 0.56]
Sacco, 2009	3	7.40 1.12 21	7.80 1.30 27			12.0% -0.40 [ -1.09 , 0.29 ]
Browning, 2014	3	6.88 0.88 48	7.16 1.16 48	-	-	18.6% -0.28 [ -0.69 , 0.13 ]
Ruggiero, 2014	3	8.45 1.36 95	7.89 1.46 85		_ <b>_</b> _	18.6% 0.56 [ 0.15 , 0.98 ]
Wayne, 2015	3	-0.64 1.04 48	-0.97 1.40 49		<b></b>	16.5% 0.33 [-0.16, 0.82]
Summary (I2 = 63.3%	6, Q = 13.6, P=0.018)				<u> </u>	100% 0.01 [-0.39, 0.41]
Ruggiero, 2010	2	8.31 1.40 25	8.66 1.55 25	-		17.7% -0.35 [ -1.17 , 0.47 ]
Thom, 2013	2	-1.07 2.80 122	-0.30 3.10114	-	<u>—</u> į	19.6% -0.77 [ -1.53 , -0.01 ]
Cinar, 2014	2	6.70 1.53 76	7.70 1.58101	<b></b>		31.7% -1.00 [ -1.46 , -0.54 ]
Varney, 2014	2	8.20 1.02 35	8.40 1.03 36	-	-	30.9% -0.20 [ -0.68 , 0.28 ]
Summary (I2 = 51.0%	6, Q = 6.1, P=0.11)				-	100% -0.59 [ -1.22 , 0.04 ]
McMurray, 2002	0-1	6.30 1.31 45	7.20 1.66 38	· · · · · ·	<b>–</b>	15.9% -0.90 [ -1.55 , -0.25 ]
Blackberry, 2013	0-1	7.85 1.24221	7.91 1.42219		<b>⊢</b>	40.7% -0.06 [ -0.31 , 0.19 ]
Karhula, 2015	0-1	7.29 0.74156	7.40 0.74 61		<b>⊢</b> ■	43.4% -0.11 [ -0.33 , 0.11 ]
Summary (I2 = 64.7%	6, Q = 5.7, P=0.059)					100% -0.22 [ -1.12 , 0.69 ]
				Favors Health Coaching	Favors Control	
			4	2.00 -1.00	0.00 1.0	0
	Mean Difference					

## Effects on Cardiovascular Health

Six of the eligible RCTs examined the impact of health coaching on one or more cardiovascular outcomes across the chronic disease conditions. Results are grouped by key moderators of interest and then by the 2 prioritized outcomes of systolic blood pressure and cholesterol. Due to variability in reported outcomes, findings are synthesized qualitatively.

#### Variation by Population Characteristics

Systolic blood pressure. Five studies reported the impact of health coaching on systolic blood pressure across the following conditions: cardiovascular disease,<sup>53</sup> hypertension,<sup>16,51</sup> coronary artery disease or congestive heart failure,<sup>41</sup> or a mixture of conditions.<sup>59</sup> Only the 2 studies that examined the effects of health coaching on cardiovascular outcomes in patients with hypertension found a positive impact on this outcome.<sup>16,51</sup> The other 3 studies in the following populations found no significant effect of health coaching on systolic blood pressure outcomes: cardiovascular disease,<sup>53</sup> coronary artery disease or congestive heart failure,<sup>41</sup> and mixed population (patients with one or more of uncontrolled diabetes, hypertension, or hyperlipidemia).<sup>59</sup>

<u>Cholesterol</u>. Four of the 6 studies examined the impact of health coaching on change in cholesterol across these conditions: cardiovascular disease, <sup>52,53</sup> coronary artery disease or congestive heart failure, <sup>41</sup> and mixed population. <sup>59</sup> Results were mixed. Both studies conducted in populations with cardiovascular disease demonstrated positive results only on changes in cholesterol, <sup>27,52,53</sup> while the other 2 studies conducted in mixed populations did not yield statistically significant findings. <sup>41,59</sup> Table 11 summarizes the finding for both systolic blood pressure and cholesterol.

Table 11. Impact of Health Coaching on Key Cardiovascular Outcomes by Population

	Systolic Blood F	Pressure (n=5)	Cholesterol (n=4)		
Population	Positive Effect Studies	No Effect Studies	Positive Effect Studies	No Effect Studies	
Hypertension	2	0	0	0	
Cardiovascular disease	0	1	2	0	
Coronary artery disease/ congestive heart failure	0	1	0	1	
Mixed population	0	1	0	1	

#### Variation by Dose

<u>Systolic blood pressure</u>. Of the 5 studies that reported systolic blood pressure outcomes, 3 studies had 10 or more planned contacts (range 11 to 20)<sup>16,41,59</sup> and 2 had fewer than 10 contacts (range 5 to 6).<sup>36,51,53</sup> Results were mixed; only one of the 3 interventions with 10 or more contacts had positive findings.<sup>16</sup> Similarly, only one of the 2 interventions with fewer than 10 contacts had a positive impact on systolic blood pressure.<sup>51</sup>

<u>Cholesterol</u>. Of the 4 studies that reported cholesterol outcomes, 2 had 10 or more planned contacts, <sup>41,59</sup> and 2 had fewer than 10 planned contacts. <sup>52,53,55</sup> No clear pattern emerged; both studies that had more contacts did not product a significant impact on cholesterol, while the

group with the smaller dose produced one study with statistically significant findings.<sup>53</sup> Table 12 summarizes the finding for both systolic blood pressure and cholesterol.

Table 12. Impact of Health Coaching on Key Cardiovascular Outcomes by Intervention Dose

Number of planned	Systolic Blood I	Pressure (n=5)	Cholesterol (n=4)		
Number of planned contacts	Positive Effect Studies	No Effect Studies	Positive Effect Studies	No Effect Studies	
Fewer than 10 planned contacts	1	1	1	1	
10 or more planned contacts	1	2	0	2	

## Variation by Mode

<u>Systolic blood pressure</u>. Of the 5 trials that assessed systolic blood pressure, 2 studies used primarily in-person health coaching, <sup>16,59</sup> and 3 studies used primarily phone-based coaching. <sup>41,51,53</sup> Across both modes of delivery, results were mixed. Only one phone-delivered study<sup>51</sup> and one in-person study<sup>16</sup> produced significant impacts on systolic blood pressure.

<u>Cholesterol</u>. Of the 4 trials that assessed changes in cholesterol, only one study used primarily inperson health coaching, <sup>59</sup> and 3 studies used primarily phone-based coaching. <sup>41,52,53</sup> Again, results were mixed. Only 2 phone-based studies produced significant effects. <sup>52,53</sup> Table 13 summarizes the finding for both systolic blood pressure and cholesterol.

**Table 13. Impact of Health Coaching on Key Cardiovascular Outcomes by Intervention Delivery Mode** 

	Systolic Blood P	ressure (n=5)	Cholesterol (n=4	Cholesterol (n=4)		
Mode of Delivery	Positive Effect Studies	No Effect Studies	Positive Effect Studies	No Effect Studies		
In-person health coaching	1	1	0	1		
Phone-based health coaching	1	2	2	1		

#### Variation by Type of Coach

Systolic blood pressure. Of the 5 trials that assessed systolic blood pressure, 3 studies used healthcare providers (*ie*, nurse or medical assistant) to deliver the coaching intervention. 41,53,59 One study used a peer coach,<sup>51</sup> and another used a trained health educator. There was a consistent pattern of effects. The 3 interventions delivered by a healthcare provider did not have significant effects on systolic blood pressure, while the 2 interventions delivered by a non-healthcare provider did report significant effects of health coaching on systolic blood pressure.

<u>Cholesterol</u>. All 4 studies that reported cholesterol outcomes used some form of a healthcare provider, including nurse, <sup>41,53</sup> dietician, <sup>52</sup> or medical assistant, <sup>59</sup> to deliver the coaching intervention. No clear pattern emerged from the data. Only one of the 2 nurse-led interventions reported a positive impact on cholesterol. <sup>53</sup> The other study with a positive outcome was





delivered by a dietician.<sup>52</sup> Table 14 summarizes the finding for both systolic blood pressure and cholesterol.

Table 14. Impact of Health Coaching on Key Cardiovascular Outcomes by Type of Individual Conducting Coaching Intervention

	Systolic Blood	Pressure (n=5)	Cholesterol (n=4)		
Coach Type	Positive Effect Studies	No Effect Studies	Positive Effect Studies	No Effect Studies	
Healthcare provider	0	3	2	2	
Peer coach and/or trained health educator	2	0	0	0	

## Variation by Concordance

Systolic blood pressure. The 5 studies of health coaching that reported impacts on systolic blood press had the following range of concordance scores: one study each for a score of 1,<sup>41</sup> 2,<sup>16</sup> or 3,<sup>51</sup> and 2 studies with a score of 4.<sup>53,59</sup> No clear pattern emerged. Of the trials reporting no statistically significant effects, one had a concordance score of 1,<sup>41</sup> and 2 had the highest possible concordance score of 4.<sup>53,59</sup> The 2 positive studies had concordance scores of 2<sup>16</sup> and 3.<sup>51</sup>

<u>Cholesterol</u>. The 4 studies of health coaching that reported impacts on cholesterol had the following concordance scores: one study with a scores of 1<sup>41</sup> and 3 studies with a score of 4.<sup>49,52,53,59</sup> Similar to systolic blood pressure, no clear pattern of effects emerged by concordance score. While both positive impact studies had scores of 4, a no impact study also had a score of 4.<sup>59</sup> The only consistent finding was that, across both outcomes, the study with the concordance score of 1 did not have a statistically significant impact on either of the prioritized cardiovascular outcomes. Table 15 summarizes the finding for both systolic blood pressure and cholesterol.

Table 15. Impact of Health Coaching on Key Cardiovascular Outcomes by Concordance Score

	Systolic Blood F	Pressure (n=5)	Cholesterol (n=4)		
Concordance Score	Positive Effect Studies	No Effect Studies	Positive Effect Studies	No Effect Studies	
1	0	1	0	1	
2	1	0	0	0	
3	1	0	0	0	
4	0	2	2	1	

#### Effects on Functional Status

Two of the eligible RCTs examined the impact of health coaching interventions on functional status compared with inactive controls. Functional status was examined as both a self-reported outcome in one study and as an objective 6-minute walk test in another. Results are grouped by key moderators of interest and summarized qualitatively.



## Variation by Population Characteristics

Both coaching interventions that reported effects on functional status sought to increase physical activity in individuals with physically disabling conditions or rheumatoid arthritis<sup>35</sup> and multiple sclerosis.<sup>47</sup> Results were mixed. The study of patients with multiple sclerosis found a positive effect of health coaching on functional status.<sup>47</sup> However, the study of patients with rheumatoid arthritis demonstrated no positive effect of health coaching on functional status, as indicated by self-reported disability scores.<sup>35</sup>

# Variation by Dose of Intervention

One study had fewer than 10 planned contacts<sup>35</sup> and one study had 10 or more planned contacts.<sup>47</sup> The latter study, with 15 planned contacts,<sup>47</sup> found a positive effect of health coaching on functional status, while the other study did not.<sup>35</sup>

## Variation by Mode of Delivery

One study delivered the health coaching intervention via video chat using Skype and found a positive effect of health coaching on functional status. <sup>47</sup> The second study delivered the health coaching intervention using a mix of in-person group sessions and individual phone calls but did not find a positive effect of health coaching on functional status. <sup>35</sup>

## Variation by Type of Individual Conducting Coaching Intervention

One study did not report on the type of personnel used as a coach.<sup>47</sup> The second study used healthcare providers to deliver the health coaching intervention.<sup>35</sup> No positive effects on functional status were found.

## Variation by Concordance

Both studies demonstrated low concordance with key health coaching elements, with scores of 1<sup>47</sup> and 2.<sup>35</sup> The study with lower concordance was the only study to find a positive effect of health coaching on functional status.<sup>47</sup>

## **Detailed Findings for Patient Health Behaviors**

In this section, we describe findings by effects of health coaching on physical activity, weight management, smoking, and medication adherence.

## Effects on Physical Activity

Seventeen of the eligible RCTs examined the impact of health coaching on physical activity. <sup>20,21,25,26,29-32,35,43,45,47,48,54,55,58,61</sup> We organize the findings based on the subgroups for the outcome physical activity as follows: (1) physical activity change (a continuous variable representing steps or minutes of exercise) and (2) physical activity threshold (a continuous variable representing achievement of some threshold of exercise). The 15 studies that were amenable to meta-analysis were assessed to see if effects on physical activity varied by the key moderators.

#### Variation by Population Characteristics

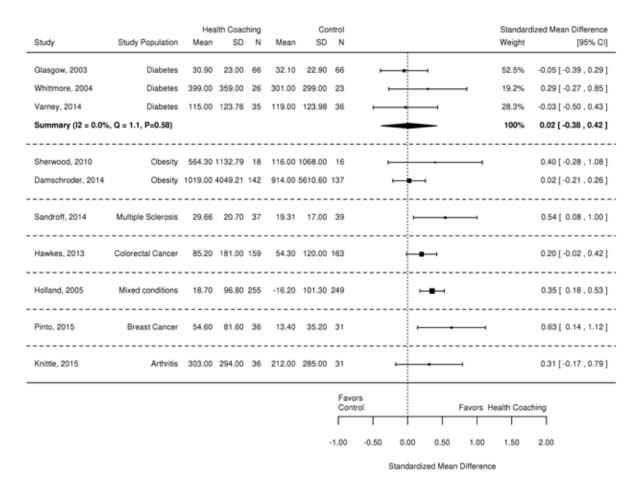
<u>Physical activity change.</u> Change was reported in the following medical conditions: diabetes<sup>30,55,58</sup> (n=3), obesity<sup>29,61</sup> (n=2), multiple sclerosis<sup>47</sup> (n=1), breast cancer<sup>43</sup> (n=1),





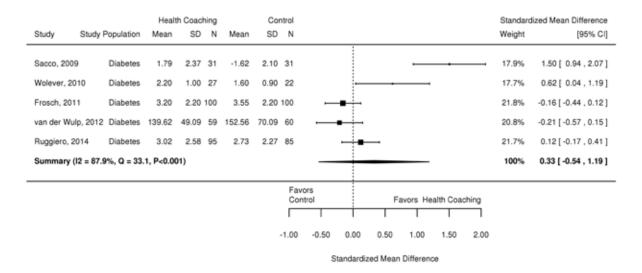
colorectal cancer<sup>31</sup> (n=1), arthritis<sup>35</sup> (n=1), and mixed conditions<sup>32</sup> (n=1). Figure 16 shows the forest plot organized by medical condition. Studies showed that same trend of a positive impact of health coaching on physical activity change; however, across the 7 populations, there were major differences in effect sizes (SMD range 0.02 to 0.63). No clear pattern of effects by population emerged; subgroups with more than one study produced a mix of significant and not significant results.

Figure 16. Effect of Health Coaching on Physical Activity Change by Population Characteristics



<u>Physical activity threshold.</u> Threshold was reported in 5 studies<sup>20,21,45,54,61</sup>; all 5 were conducted among populations with diabetes. Thus we were not able to explore the differential impact of health coaching by population on physical activity threshold (Figure 17).

Figure 17. Effect of Health Coaching on Physical Activity Threshold by Population Characteristics

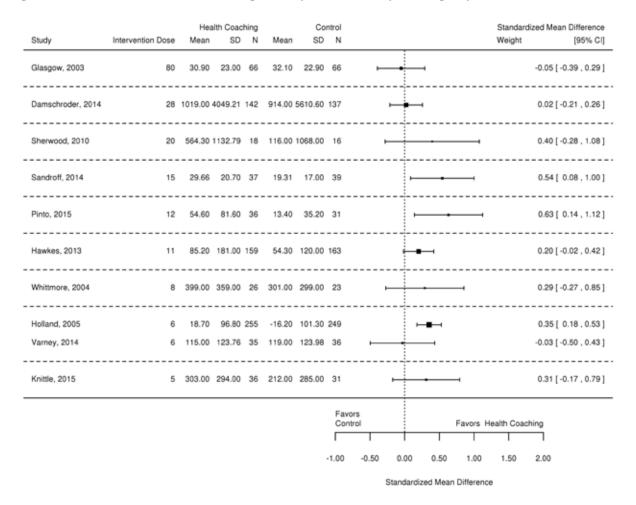


Two additional trials assessed physical activity threshold through categorical variables and therefore could not be combined with the studies above. Neither study found statistically significant impacts of health coaching on threshold. In brief, one study<sup>25</sup> examined the effects of health coaching on physical activity in adult females with systemic lupus erythematosus and found no statistically significant differences between the intervention and inactive control groups. A second study<sup>26</sup> assessed the effects of health coaching on physical activity in patients with rheumatoid arthritis. Although the intervention group increased the number of patients who attained the physical activity "health goal," the increase was not significantly different from the increase in the control group.

#### Variation by Dose

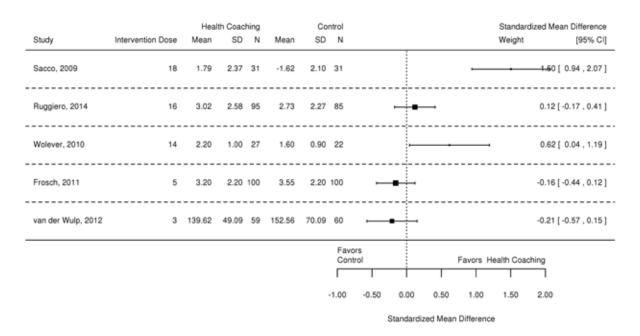
<u>Physical activity change</u>. Change was reported in 10 studies  $^{29\text{-}32,35,43,47,48,55,58}$  whose "intervention dose" ranged from 5 to 80 planned sessions of health coaching. Figure 18 shows the forest plot organized by number of sessions. The SMD range was -0.05 to 0.63. With one exception (SMD -0.03; 95% -0.50 to 0.43),  $^{55}$  all studies with 20 or fewer planned sessions showed a small positive effect of intervention dose on health coaching (all SMD  $\geq$ 0.20). Three of these results,  $^{32,43,47}$  with intervention doses of 6, 12, or 15 sessions, were significant. Conversely, 2 studies with the highest numbers of planned sessions, 28 and 80, found negligible effect sizes (SMD-0.05 and 0.02) that were not significant.

Figure 18. Effect of Health Coaching on Physical Activity Change by Intervention Dose



<u>Physical activity threshold.</u> Threshold was reported in 5 studies<sup>20,21,45,54,61</sup> whose intervention dose ranged from 3 to 18 planned sessions. Figure 19 shows the forest plot organized by number of sessions. Two studies<sup>21,54</sup> had fewer than 6 planned sessions and exhibited negative effects (SMDs -0.16 and -0.21) that were not significant. The other three studies<sup>20,45,61</sup> had 14 to 18 planned sessions and exhibited positive effects (SMDs 0.12 to 1.50), 2 of which were significant.<sup>45,61</sup>

Figure 19. Effect of Health Coaching on Physical Activity Threshold by Intervention Dose

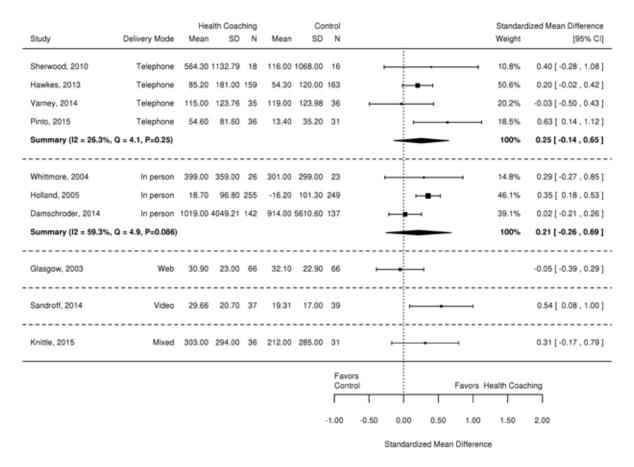


The 2 trials that assessed physical activity threshold through categorical variables have been described previously. Both had an average of 12 planned sessions. In brief, one study<sup>25</sup> provided individual coaching every 6 weeks for 3 months decreasing over a year. The other study<sup>26</sup> provided monthly coaching sessions. Neither found a statistically significant difference between the intervention and control groups on physical activity.

## Variation by Mode

Physical activity change. Change was reported in 10 studies<sup>29-32,35,43,47,48,55,58</sup> wherein mode of delivery was sorted into 5 categories: telephone<sup>31,43,48,55</sup> (n=4), in-person<sup>29,32,58</sup> (n=3), web<sup>30</sup> (n=1), video<sup>47</sup> (n=1), and mixed<sup>35</sup> (n=1). Figure 20 shows the forest plot organized by type of delivery mode. Across the delivery modes, there were differences in effect sizes (SMD range -0.05 to 0.54). Meta-analysis was possible for 2 types of delivery mode, telephone and in-person; both subgroups displayed a similar magnitude of effects, but neither pooled estimate was significant. The other 3 modes examined had only one eligible trial each. One of these studies, one showed a moderate positive effect of health coaching via video that was significant.<sup>47</sup> The other 2 studies, which used the web<sup>30</sup> and "mixed" mode of delivery,<sup>35</sup> found negligible to small effect sizes that were not significant.

Figure 20. Effect of Health Coaching on Physical Activity Change by Mode of Delivery



<u>Physical activity threshold.</u> Threshold was reported in 5 studies, <sup>20,21,45,54,61</sup> all with inactive comparators, 4 of which used the telephone as the mode of delivery <sup>20,21,45,61</sup> while one used inperson as the mode of delivery. <sup>54</sup> The 2 types of delivery modes produced effects that were different in magnitude and direction. The pooled estimate for the 4 telephone-delivered studies produced a small, positive effect that was not statistically significant. The one study that used inperson health coaching as the mode of delivery found a small negative effect for in-person coaching that was not significant (Figure 21).

Health Coaching Control Standardized Mean Difference Delivery Mode Mean Study SD N SD N Mean Weight [95% CI] Sacco, 2009 Telephone 2.37 31 -1.62 2.10 31 23.1% 1.50 [ 0.94 , 2.07 ] Wolever, 2010 0.90 22 22.9% 0.62 [ 0.04 , 1.19 ] Telephone 2.20 1.00 27 1.60 Frosch, 2011 2.20 100 3.55 2.20 100 -0.16 [ -0.44 , 0.12 ] Ruggiero, 2014 Telephone 3.02 2.58 95 2.27 85 0.12 [ -0.17 , 0.41 ] Summary (I2 = 89.7%, Q = 29.3, P<0.001) 0.48 [ -0.67 , 1.63 ] van der Wulp, 2012 in person 139.62 49.09 59 152.56 70.09 60 -0.21 [ -0.57 , 0.15] Favors Health Coaching -0.500.00 0.50

Figure 21. Effect of Health Coaching on Physical Activity Threshold by Mode of Delivery

The 2 trials that assessed physical activity threshold through categorical variables have been described previously. One study<sup>26</sup> provided in-person coaching sessions, while the other study<sup>25</sup> provided coaching via phone. Neither study found a statistically significant difference between the intervention and inactive control groups on physical activity, which is congruent with the findings reported above.

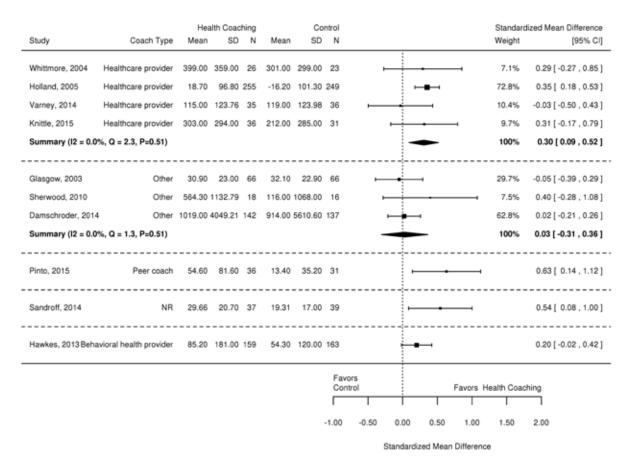
Standardized Mean Difference

Variation by Type of Individual Conducting Coaching Intervention

Physical activity change. Change was reported in 10 studies that used the following types of individuals as coaches: healthcare provider<sup>32,35,55,58</sup> (n=4), "other"<sup>29,30,48</sup> (n=3), behavioral health provider<sup>31</sup> (n=1), peer coach<sup>43</sup> (n=1), and "not reported"<sup>47</sup> (n=1). Figure 22 shows the forest plot organized by type of coach. Across the coach types, effect sizes were consistently positive although varying in magnitude and statistical significance (SMD range: 0.03 to 0.63). There were 2 categories of coach type, healthcare provider and "other," for which there were enough studies to perform a meta-analysis. The meta-analysis for healthcare provider (n=4) found a significant positive effect for health coaching on physical activity (SMD 0.30; 95% CI 0.09 to 0.52) with negligible heterogeneity ( $I^2$ =0.0%). The meta-analysis for "other" provider type found a negligible effect of health coaching on physical activity (SMD 0.03; 95% CI -0.31 to 0.36) that was not significant.

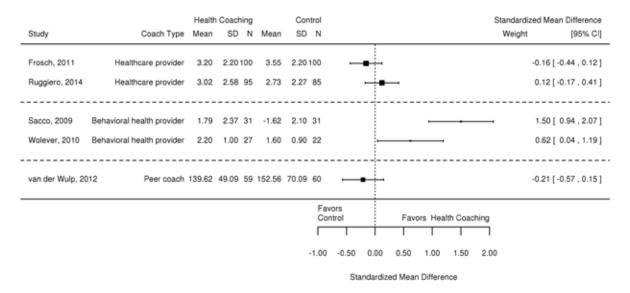
There was one study each for peer coaches,<sup>43</sup> behavioral health providers,<sup>31</sup> and unidentified type of coach.<sup>47</sup> All found a small to a moderate positive effect of health coaching (SMD range 0.20 to 0.63), but only the peer coach study and the unidentified type of coach study produced moderate effect sizes that were statistically significant. The third study found a small, positive effect that was not significant for behavioral health providers.

Figure 22. Effect of Health Coaching on Physical Activity Change by Type of Coach



<u>Physical activity threshold.</u> Threshold was reported in 5 studies<sup>20,21,45,54,61</sup>; 2<sup>20,21</sup> used healthcare providers, 2<sup>45,61</sup> used behavioral health providers, and one<sup>54</sup> used peer coaches. Results are converse to those found for physical activity change above. The 2 studies that used healthcare providers<sup>20,21</sup> both found negligible effects (SMD range -0.16 to 0.12) that were not significant. The 2 studies that used behavioral health providers<sup>45,61</sup> both found sizeable positive effects that were significant (SMD range 0.62 to 1.50). The study using peer coaches found a negative effect that was not significant (SMD -0.21) (Figure 23).

Figure 23. Effect of Health Coaching on Physical Activity Threshold by Type of Coach

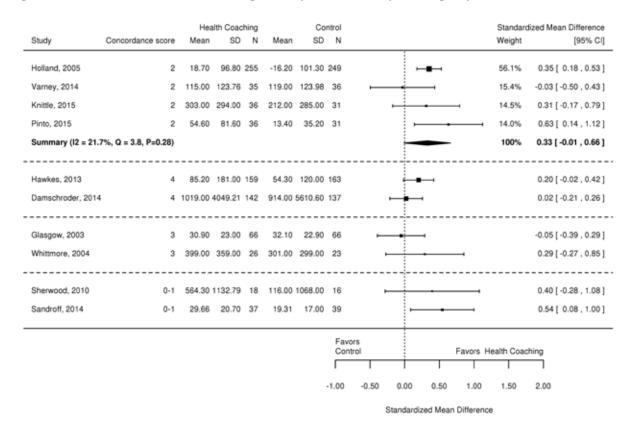


Two trials assessed physical activity threshold through categorical variables and therefore could not be combined with the other studies. <sup>25,26</sup> Both used healthcare providers as coaches and both found no significant differences between the intervention and control groups, which is consistent with the 2 continuous variable physical activity threshold studies.

## Variation by Concordance

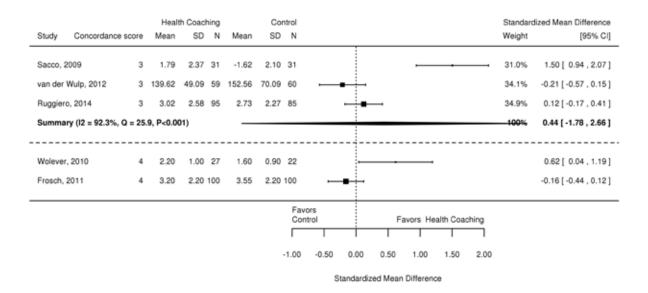
Physical activity change. Change was reported with the following concordance scores: 0-1 (n=2),<sup>47,48</sup> 2 (n=4),<sup>32,35,43,55</sup> 3 (n=2),<sup>30,58</sup> and 4 (n=2).<sup>29,31</sup> Figure 24 shows the forest plot organized by concordance score. Across the 4 scores, there were major differences in effect sizes (SMD range -0.05 to 0.54), but they did not form any type of consistent pattern by level of concordance score.

Figure 24. Effect of Health Coaching on Physical Activity Change by Concordance



<u>Physical activity threshold.</u> Threshold was reported in 5 studies, <sup>20,21,45,54,61</sup> all of which had a concordance score of either 3 (n=3)<sup>20,45,54</sup> or 4 (n=2).<sup>21,61</sup> Again, no clear pattern emerged by level of concordance (Figure 25).

Figure 25. Effect of Health Coaching on Physical Activity Threshold by Concordance



The 2 trials<sup>25,26</sup> that assessed physical activity threshold through categorical variables both had concordance scores of 0-1, and both found no significant differences between the intervention and control groups. This is different from the results for physical activity change, but still adds evidence to no specific pattern of effect for concordance score on physical activity change.

# Effects on Weight Management

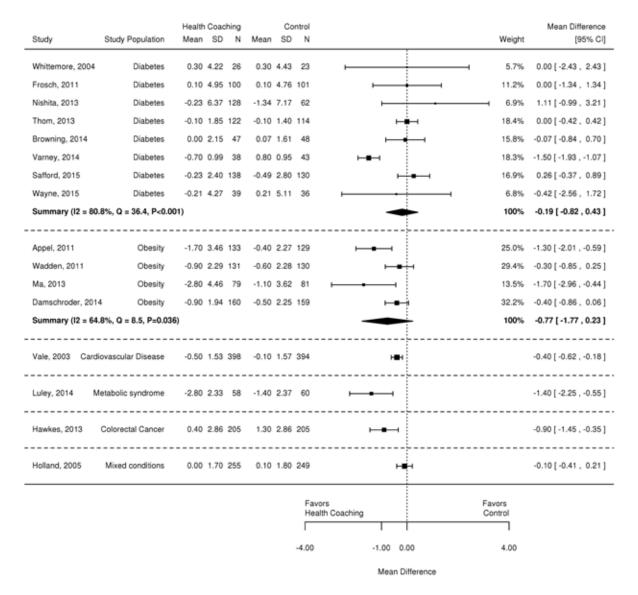
Twenty of the eligible RCTs examined the impact of health coaching on weight in pounds or kilograms (n=12), body mass index (BMI) (n=16), or both (n=8). 19,21,23,24,27,29,31-33,36,37,40,46,48,49,53,55-58 As change in BMI was the most common metric across the 20 studies, we conducted quantitative synthesis for this outcome and stratified studies by the key moderators of interest. We provide a qualitative synthesis of findings for the 4 trials that reported outcomes as change in weight in kilograms or pounds only and could not be pooled with the other studies.

# Variation by Population Characteristics

<u>Change in BMI</u>. Change was reported in the following medical conditions: diabetes  $^{21,27,40,46,49,55,57,58}$  (n=8), obesity  $^{23,29,37,56}$  (n=4), cardiovascular disease  $^{53}$  (n=1), metabolic syndrome  $^{36}$  (n=1), colorectal cancer  $^{31}$  (n=1), and "mixed conditions"  $^{32}$  (n=1). Figure 26 shows the forest plot organized by medical condition. No clear pattern of effects emerged. All subgroups demonstrated the same direction of effects. However, across the 6 populations, there were major differences in magnitude of effect sizes (MD range -1.40 to -0.10). Both pooled estimates of the diabetes and obesity subgroups displayed moderate to high heterogeneity as exhibited by an  $I^2 > 50\%$ .



Figure 26. Effect of Health Coaching on Change in BMI by Population Characteristics



Change in weight in kilograms. There were 4 additional studies that presented data on weight in kilograms but not on BMI. 19,24,33,48 These findings are synthesized qualitatively. Two studies were conducted in patients with obesity, 19,48 one was conducted in patients with type 2 diabetes, 24 and one study looked at the effect of the same intervention on 2 populations, one with type 2 diabetes and one with cardiovascular disease (CVD). 33 Congruent with the BMI studies, no clear pattern emerged. The 2 obesity studies had conflicting results; one 48 showed a positive effect of health coaching, while the other 19 displayed a positive effect for the active control group. Consistent with the findings above, neither diabetes study 24,33 found positive effects on weight loss in kilograms for health coaching. In addition, a study that also looked at CVD 33 did not find a positive effect of health coaching in this population.

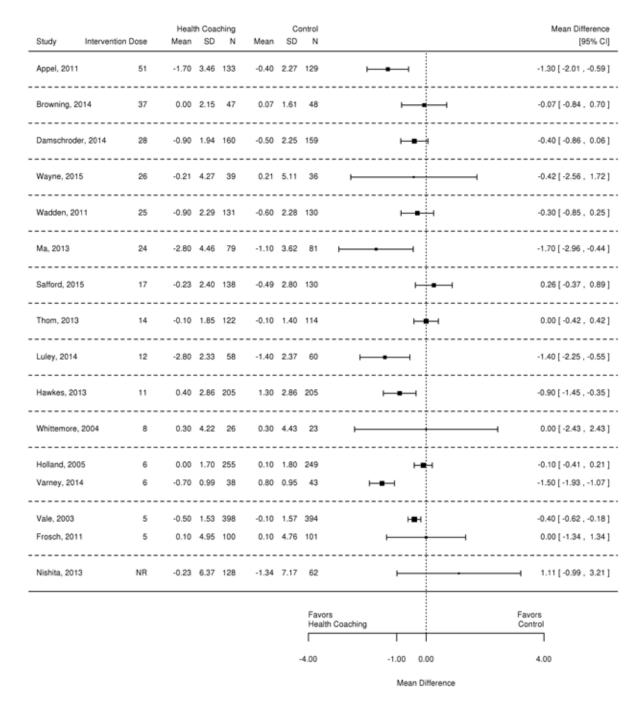
#### Variation by Dose

<u>Change in BMI</u>. The number of planned contacts ranged from 5 to 51. Figure 27 shows the forest plot organized by number of planned contacts. Dose was different for all studies except 2 sets of studies that had either 5 or 6 planned contacts. The median dose was 17 planned contacts. The



MD range was -1.70 (a study with 24 planned contacts<sup>37</sup>) to 0.26 (a study with 17 planned contacts<sup>46</sup>). No clear pattern emerged from the data to demonstrate that number of planned contacts explained variation in effects of BMI across studies.

Figure 27. Effect of Health Coaching on BMI by Intervention Dose



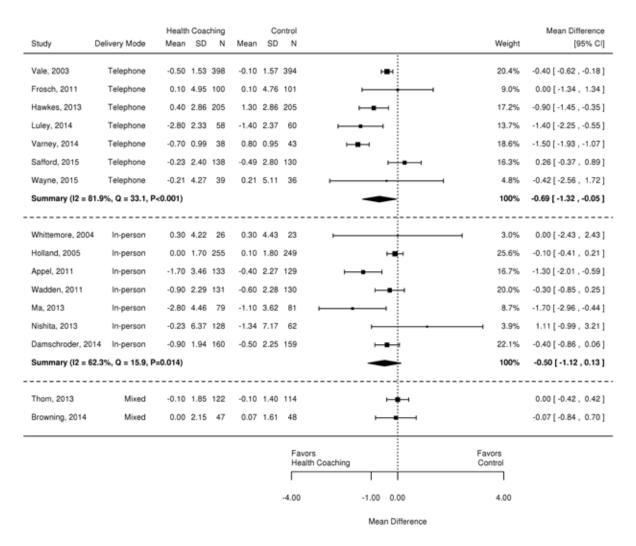
<u>Change in weight in kilograms</u>. There were 4 additional studies that presented data on change in kilograms. <sup>19,24,33,48</sup> The number of planned contacts ranged from 9 to 20 session, with a median dose was 12 planned contacts. Only the study with the greatest number of sessions (n=20) resulted in a statistically significant impact on weight change. <sup>48</sup> The other 3 studies with doses of 9 or 12 contacts did not produce significant impacts on weight change.



#### Variation by Mode

There were 3 different major modes of intervention delivery for the studies that reported changes in BMI. Seven studies used primarily telephone-based delivery, <sup>21,31,36,46,53,55,57</sup> and an additional 7 used primarily in-person coaching. <sup>23,29,32,37,40,56,58</sup> The other 2 studies used a mix of intervention delivery modes. <sup>27,49</sup> Figure 28 shows the forest plot organized by delivery mode. Both in-person and telephone delivery displayed a similar direction and magnitude of effects; however, only the telephone delivery estimate was statistically significant. Both estimates also had moderate to high heterogeneity. In contrast, the 2 studies that used a mix of intervention delivery modes displayed point estimates that were null.

Figure 28. Effect of Health Coaching on BMI by Mode of Delivery



<u>Change in weight in kilograms</u>. The 4 additional studies that presented data on weight change in kilograms<sup>19,24,33,48</sup> were all delivered via telephone. Thus, we were unable to assess the impact of intervention mode on these studies.

Variation by Type of Individual Conducting Coaching Intervention

Studies employed a variety of personnel as health coaches. Nine used a nurse or other licensed healthcare provider as the coach. <sup>21,23,27,32,36,53,55,56,58</sup> Two used a licensed behavioral health



provider,<sup>31,57</sup> and another 2 employed peer coaches.<sup>46,49</sup> The final 3 studies used a variety of other personnel as coaches (*eg*, study-trained lifestyle coach).<sup>29,37,40</sup> The direction and magnitude of effects were similar across all subgroups, except one (Figure 29). Nearly all subgroups displayed a small, positive impact on reductions in BMI. In contrast, both peer-led coaching interventions did not report reductions in BMI.

Figure 29. Effect of Health Coaching on BMI by Type of Coach

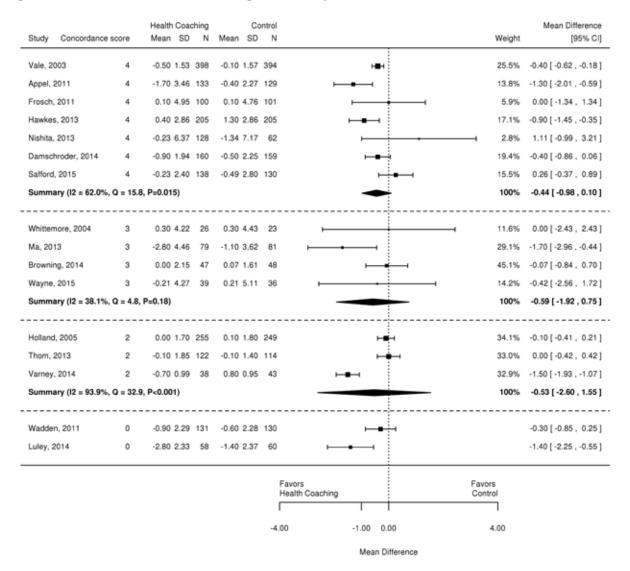
Study	Coach Type	Health Coa Mean St		Co Mean SD	ontrol N		Weight	Mean Difference [95% CI]
Vale, 2003	Healthcare provider	-0.50 1.5	3 398	-0.10 1.57	394	H <b>=</b> 1	16.4%	-0.40 [ -0.62 , -0.18 ]
Whittemore, 2004	Healthcare provider	0.30 4.2	2 26	0.30 4.43	23		2.4%	0.00 [-2.43 , 2.43]
Holland, 2005	Healthcare provider	0.00 1.7		0.10 1.80	249	H <b>=</b> H	15.7%	-0.10 [ -0.41 , 0.21 ]
Appel, 2011	Healthcare provider	-1.70 3.4	6 133	-0.40 2.27	129	<b>⊢</b>	11.3%	-1.30 [ -2.01 , -0.59 ]
Frosch, 2011	Healthcare provider	0.10 4.9	5 100	0.10 4.76	101		6.0%	0.00 [-1.34 , 1.34]
Wadden, 2011	Healthcare provider	-0.90 2.2	9 131	-0.60 2.28	130	<b>⊢</b> ■	13.1%	-0.30 [ -0.85 , 0.25 ]
Browning, 2014	Healthcare provider	0.00 2.1	5 47	0.07 1.61	48	<b></b>	10.7%	-0.07 [ -0.84 , 0.70 ]
Luley, 2014	Healthcare provider	-2.80 2.3	3 58	-1.40 2.37	60	<b>⊢</b>	9.9%	-1.40 [ -2.25 , -0.55 ]
Varney, 2014	Healthcare provider	-0.70 0.9	9 38	0.80 0.95	43	<b>⊢</b> ■→	14.5%	-1.50 [ -1.93 , -1.07 ]
Summary (I2 = 80.	.1%, Q = 40.3, P<0.001)					-	100%	-0.63 [ -1.12 , -0.15 ]
Ma, 2013	Other	-2.80 4.4	6 79	-1.10 3.62	81	<b></b>	32.4%	-1.70 [ -2.96 , -0.44 ]
Nishita, 2013	Other	-0.23 6.3	7 128	-1.34 7.17	62		19.4%	1.11 [ -0.99 , 3.21 ]
Damschroder, 2014	4 Other	-0.90 1.9	4 160	-0.50 2.25	159	<b>⊢</b> •	48.2%	-0.40 [ -0.86 , 0.06 ]
Summary (12 = 66.	.2%, Q = 5.9, P=0.052)				-		100%	-0.53 [ -3.53 , 2.47 ]
Thom, 2013	Peer	-0.10 1.8	5 122	-0.10 1.40	114			0.00 [-0.42 , 0.42]
Safford, 2015	Peer	-0.23 2.4		-0.49 2.80		-		0.26 [ -0.37 , 0.89 ]
Handra 2012 Ba	ehavioral health provider	040.00		120.200	205			0.001.145.0251
	ehavioral health provider	0.40 2.8 -0.21 4.2		1.30 2.86 0.21 5.11				-0.90 [-1.45 , -0.35 ] -0.42 [-2.56 , 1.72 ]
					Favo	ors th Coaching	Favors Control	
						<del>- 1  </del>		
					4.00	-1.00 0.00	4.00	
						Mean Difference		

<u>Change in weight in kilograms</u>. The 4 additional studies that presented data on weight change in kilograms <sup>19,24,33,48</sup> were all delivered by the following: certified health coach, <sup>19</sup> study-trained coach, <sup>33</sup> nurse, <sup>24</sup> and a coach with an unspecified training or discipline. <sup>48</sup> We were unable to assess the impact of intervention mode on these studies. Only the study with the coach of unclear training produced a statistically significant impact on reductions in weight. <sup>48</sup>

## Variation by Concordance

Figure 30 shows the forest plot organized by concordance score. Qualitatively, no consistent pattern of effects by level of concordance score were found. All 3 pooled estimates for concordance scores of 4, 3, or 2 displayed a similar magnitude and direction of effects and one of the 2 studies with a concordance score of 0 produced one of the largest point estimates.<sup>36</sup>

Figure 30. Effect of Health Coaching on BMI by Concordance



Change in weight in kilograms. The 4 additional studies that presented data on weight change in kilograms <sup>19,24,33,48</sup> had the following concordance scores: 2 had scores of 0, <sup>33,48</sup> one had a score of 1, <sup>24</sup> and one had a score of 4. <sup>19</sup> Similar to the findings for BMI, no consistent pattern of effects by concordance score emerged. The only study with a statistically significant impact on reductions in weight <sup>48</sup> had a concordance score of 0 while studies with scores of 4 did not produce significant impacts on weight loss.

### Effects on Smoking Cessation

Two of the eligible RCTs examined the impact of health coaching on smoking behavior. <sup>31,53</sup> Neither trial found an effect of health coaching on smoking behavior. Thus we were unable to explore variations in effects by the key moderators of interest.

# Effects on Medication Adherence

Three of the eligible RCTs examined the impact of health coaching on medication adherence outcomes in patients with diabetes.<sup>21,59,61</sup> Below we explore variations in effects by the key moderators.

#### Variation by Population Characteristics

All 3 studies examined the effects of health coaching on medication adherence in patients with type 2 diabetes. <sup>21,59,61</sup> Thus we were unable to assess variation by population.

#### Variation by Dose

One study had fewer than 10 planned contacts<sup>21</sup> and 2 studies had 10 or more planned contacts.<sup>59,61</sup> The study with the highest number of planned contacts (16 contacts) was the only study to find a positive effect of health coaching on medication adherence.<sup>59</sup>

## Variation by Mode

Of the 3 studies that focused on medication adherence, one delivered the health coaching intervention in-person and found a positive effect on the outcome of interest.<sup>59</sup> The remaining 2 studies delivered the intervention via telephone and did not find a positive effect of health coaching on medication adherence.<sup>21,61</sup>

#### Variation by Type of Individual Conducting Coaching Intervention

All 3 studies used behavioral or healthcare providers to deliver the health coaching intervention. One study used trained medical assistants and found a positive effect of health coaching on medication adherence.<sup>59</sup> The remaining 2 studies used either trained nurse educators<sup>21</sup> or behavioral health providers (social workers or master's-level psychologists).<sup>61</sup> Neither study found a positive effect of health coaching on medication adherence.

#### Variation by Concordance

All 3 studies had a concordance score of 4; thus we were unable to assess variation by this moderator. <sup>21,59,61</sup>

# **Detailed Findings for Self-efficacy**

Eight of the eligible RCTs examined the impact of health coaching interventions on self-efficacy outcomes. <sup>22,24,34,35,45,54,62,63</sup> All 8 studies used questionnaires with continuous scales and were





therefore amenable for quantitative synthesis. However, there was substantial variability in the questionnaires used to measure self-efficacy, so all summary estimates were calculated as SMDs.

# Variation by Population Characteristics

To assess whether the effects of health coaching interventions vary by the medical condition of the population, we classified studies and organized findings by the following populations: diabetes<sup>24,34,40,54,62</sup> (n=6), obesity,<sup>22</sup> (n=1) and arthritis (n=1).<sup>35</sup> We had sufficient studies to perform one meta-analysis on the group with diabetes. The other comparisons were synthesized qualitatively.

Figure 31 shows the forest plot of the meta-analysis and other effect sizes. Across the 3 populations, all effect sizes were positive and statistically significant, but varied in magnitude (SMD range 0.38 to 0.68). The pooled estimate for diabetes showed a small, positive effect size compared to the moderate effect sizes for the other 2 studies.

Health Coaching Control Standardized Mean Difference Study Population Study Mean SD N Mean SD N Weight [95% CI] 352.42 163.48 31 0.41 [ -0.09 , 0.91 ] Sacco, 2009 422.97 176.40 31 10.1% Diabetes 15.2% 0.21 [ -0.15 , 0.57 ] Van der Wulp, 2012 Diabetes 74.80 11.67 71.82 15.86 60 Blackberry, 2013 81.23 10.96 175 79.94 11.46 194 23.7% 0.11 [-0.09, 0.32] Nishita, 2013 0.53 [ 0.22 , 0.83 ] 4.19 0.68 128 0.63 62 17.8% Diabetes 3.84 13.7% 0.53 [ 0.13, 0.93] Young, 2014 Diabetes 4.03 0.60 51 3.64 0.84 50 Kim, 2015 Diabetes 9.50 12.30 105 1.80 13.26 104 19.4% 0.60 [ 0.32, 0.88] Summary (I2 = 54.0%, Q = 10.9, P=0.054) Annesi, 2011 Obesity 17.81 3.92 63 15.63 3.65 114 0.58 [ 0.27, 0.89] Knittle, 2015 Arthritis 95.80 27.49 36 76.80 27.49 31 0.68[0.19,1.18] Control Favors Health Coaching Г -0.50 0.00 0.50 1.00 1.50

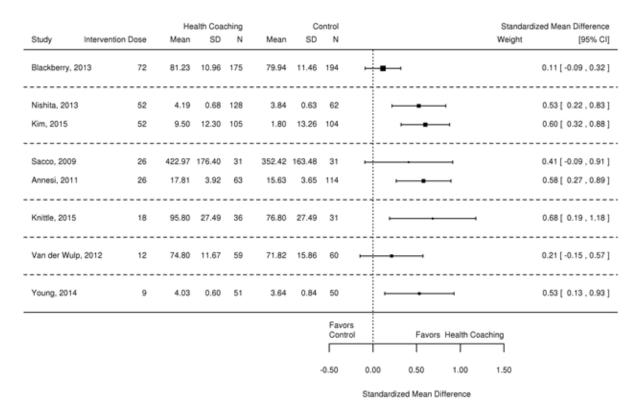
Figure 31. Effect of Health Coaching on Self-efficacy by Population Characteristics

#### Variation by Dose

To assess whether the effects of health coaching vary by intervention dose, we organized studies by number of planned sessions (range 9 to 72). Over the range of sessions, all SMDs found a small to moderate effect of health coaching on self-efficacy (SMD Range 0.11 to 0.68) and 6 of these results were significant. Figure 32 shows the forest plot for different intervention doses. The forest plot does not show any clear pattern by intervention dose.

Standardized Mean Difference

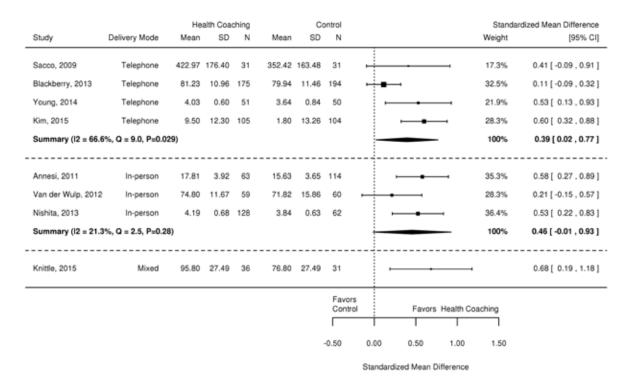
Figure 32. Effect of Health Coaching on Self-efficacy by Intervention Dose



#### Variation by Mode

To assess whether the effects of health coaching interventions vary by the mode of delivery, we classified interventions as delivered either via telephone<sup>24,34,45,62</sup> (n=4), in-person<sup>22,40,54</sup> (n=3), or using mixed modes<sup>35</sup> (n=1). Across the 3 subgroups, all effect sizes were in the same direction and of a similar small to moderate effect size (SMD range 0.39 to 0.68). Two were statistically significant (telephone and mixed mode) while the other trended toward significance (in-person) (Figure 33).

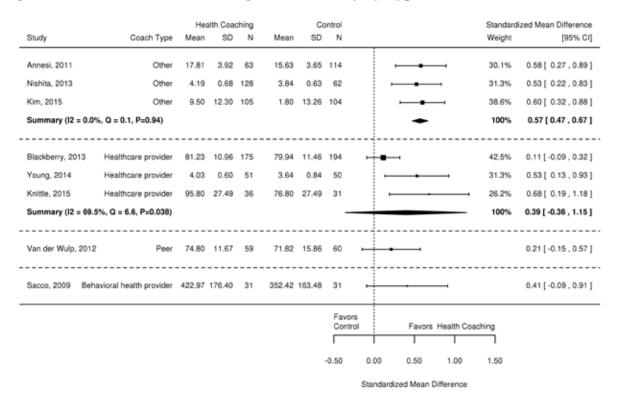
Figure 33. Effect of Health Coaching on Self-efficacy by Mode of Delivery



Variation by Type of Individual Conducting Coaching Intervention

To assess whether the effects of health coaching vary by the discipline of or type of training received by the coaches, we classified studies by type of interventionist: healthcare providers<sup>22,34,40</sup> (n=3), "other"<sup>24,35,62</sup> (n=3), behavioral health provider<sup>45</sup> (n=1), or peer coaches<sup>54</sup> (n=1). Across the 4 populations, all effect sizes were positive and of a similar small to medium size (SMD range 0.21 to 0.57), but only the "other" coach type subgroup was statistically significant (Figure 34).

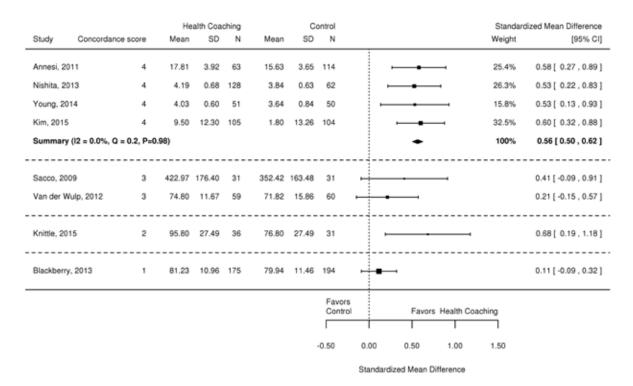
Figure 34. Effect of Health Coaching on Self-efficacy by Type of Coach



#### Variation by Concordance

We classified studies by the concordance score (range 0-4) received in relation to the number of our key elements of health coaching contained. Four studies<sup>22,34,40,62</sup> contained all 3 elements, scoring 4. Two studies received a score of 3<sup>45,54</sup> and one study each a score of 2<sup>35</sup> or 1.<sup>24</sup> Figure 35 shows the forest plot grouped by concordance scores. Across the score categories, effect sizes were positive (SMD range 0.11 to 0.68), 2 of which were statistically significant. These results, however, do not show evidence of any linear pattern related to concordance score.

Figure 35. Effect of Health Coaching on Self-efficacy by Concordance



# Quality of Evidence for KQ 2

The same studies were included for KQs 1 and 2. The quality of evidence is discussed above in the KQ 1 section.

# **SUMMARY AND DISCUSSION**

Chronic medical conditions are common among VA healthcare system users, with nearly 75% of VA users having two or more chronic conditions. Optimizing beneficial health behaviors such as medication adherence, uptake of healthy diets, regular physical activity, and improving weight management can improve outcomes associated with chronic medical conditions. 4-67 Yet, initiating and maintaining one or more health behavior changes can be daunting for many patients, especially those with multiple chronic conditions who may be unsure how to prioritize and manage multiple lifestyle changes to optimize overall health outcomes.

Health coaching may be an effective tool to facilitate uptake of health behaviors among people with one or more chronic medical conditions. At its core, health coaching is a patient-centered intervention approach that uses solution-focused techniques to enhance motivation and positive action. In health coaching interventions, coaches and patients collaboratively work to identify goals informed by the values, strengths, and preferences of the patient. Patients are viewed as the experts in how to enact lasting change and overcome barriers in their lives. Communication between coach and patient focuses on motivational processes, support, and accountability to build patient self-efficacy for positive change.

The goal of this review was to examine the effectiveness of health coaching on changes in key clinical outcomes, health behaviors, and self-efficacy outcomes among populations with chronic medical conditions. In addition, this review sought to identify key program elements associated with variable intervention effects such as patients with chronic medical conditions most likely to benefit, optimal dose (*ie*, the number of coaching sessions), mode of coaching delivery, and the most effective types of people/professionals to conduct health coaching (*eg*, physicians, social workers, nurses, dieticians, peers). In collaboration with key stakeholders, we also explored whether effects varied by concordance of health coaching intervention with an *a priori* list of key elements (*ie*, concordance score).

We identified 41 unique RCTs that assessed the impact of self-identified health coaching interventions on key clinical outcomes (HbA1c [n=20], cardiovascular health [n=6], functional status [n=2]); health behavior outcomes (physical activity [n=17], weight management [n=20], diet [n=10], smoking [n=2], medication adherence [n=3]); and self-efficacy outcomes (n=8). There was significant variability in the populations studied and the interventions assessed. While most studies recruited populations with type 2 diabetes (n=18), the remaining studies recruited patients across a wide variety of chronic medical condition including mixed diagnoses of diabetes and heart disease or renal disease (n=4), obesity (n=7), heart disease only (n=4), cancer (n=2), rheumatoid arthritis (n=2), systemic lupus erythematosus (n=1), multiple sclerosis (n=1), metabolic syndrome (n=1), or chronic conditions in general (n=1). Only one study recruited VA users. <sup>29</sup> Just over half the studies used telephone as the primary intervention delivery mode. Healthcare providers were the most common type of personnel used to implement coaching interventions, and patient-centeredness was the most prevalent (68% of trials) element of health coaching identified in the included trials. Finally, 76% of trials used inactive comparators (eg, waitlist, usual care) instead of more robust active comparators.

#### STRENGTH OF EVIDENCE

Table 16 presents an overview of findings and strength of evidence (SOE) by major outcomes prioritized by key stakeholder partners. We found moderate SOE for small increases in HbA1c



(MD -0.30; 95% CI -0.50 to -0.10) and small decreases in BMI (MD -0.52; 95% CI -0.91 to -0.14) when health coaching interventions were compared with inactive controls. We found insufficient SOE for the impact of health coaching on HbA1c and BMI when compared with active control conditions.

Table 16. Summary of Intervention Effects and Strength of Evidence Ratings

Outcome and Comparison	Number of Studies (Subjects)	Domains and Ratings Pertaining to SOE	SOE and Summary Effect Estimate (95% CI)
HbA1c: Inactive Comparator	18 of 20 (2696 in meta- analysis) <sup>a</sup>	Risk of Bias: All RCTs, but some limitations due to poor study quality. Majority of RCTs were judged to be at unclear (n=12) or high (n=5) ROB. Only one study was judged to be at low ROB.	<b>Moderate</b> MD -0.30 (-0.50 to -0.10) <sup>b</sup>
		Consistency: Some inconsistency. All but one individual study estimates had the same direction of effect as the subgroup summary estimate. Magnitude of effect sizes varied across individual studies (MD range -1.0 to 0.56). Pooled estimate displayed high heterogeneity ( <i>P</i> =65.5%).	
		Directness: Direct	
		<b>Precision:</b> Some imprecision. Many of the included studies had small sample sizes. The subgroup summary estimate was precise.	
HbA1c: Active Comparator	2 of 20 (229)	<b>Risk of Bias:</b> All RCTs; one study judged to be at unclear ROB and the other at high ROB.	Insufficient MD range: -0.25 (-0.63 to 0.13)
		<b>Consistency:</b> Inconsistent, 2 studies with different direction of effects.	to 0.33 (-0.16 to 0.82)
		Directness: Direct	
		<b>Precision:</b> Imprecise. Both studies had wide confidence intervals that crossed the null.	
BMI: Inactive Comparator	14 of 16 (3627)	Risk of Bias: All RCTs, but only 2 judged to be at low ROB; most were at unclear ROB (n=8) and the remainder were at high ROB (n=4).	<b>Moderate</b> -0.52 (-0.91 to -0.41)
		<b>Consistency:</b> Some inconsistency. All but 2 individual study estimates had the same direction of effect as the subgroup summary estimate. Magnitude of effect sizes varied across individual studies (MD range -1.70 to 1.11). Pooled estimate displayed high heterogeneity ( <i>P</i> =68.5%).	
		Directness: Direct	
		<b>Precision:</b> Some imprecision. Many of the included studies had small sample sizes. The subgroup summary estimate was precise.	



Outcome and Comparison	Number of Studies (Subjects)	Domains and Ratings Pertaining to SOE	SOE and Summary Effect Estimate (95% CI)
BMI: Active Comparator	2 of 16 (394)	Risk of Bias: All RCTs, but limitations due to poor study quality; one trial was at high ROB and the other at unclear ROB.	Insufficient MD range: -0.40 (-0.86 to 0.66)
		<b>Consistency:</b> Some inconsistency. Both estimates were in the same direction and of the same magnitude (range -0.42 to -0.40).	to -0.42 (-3.80 to 2.96)
		Directness: Direct	
		<b>Precision:</b> Imprecise. One study had a very wide confidence interval and both studies had confidence intervals that crossed the null.	

<sup>&</sup>lt;sup>a</sup> Of the 18 studies that used an inactive comparator, 17 were able to be included in the meta-analysis. One additional trial (n=1129) assessed HbA1c as a dichotomous variable (in or out of control) and could not be included in the meta-analysis.<sup>41</sup>

## SUMMARY OF EVIDENCE BY KEY QUESTION

KQ 1 assessed the impact of self-identified health coaching interventions on key clinical, health behavior, and self-efficacy outcomes. Compared to inactive comparators, health coaching had a statistically significant effect on HbA1c (MD -0.30; 95% CI -0.50 to -0.10); physical activity change as measured in metrics such as step counts or minutes of activity (SMD 0.29; 0.15 to 0.43); BMI reduction (MD -0.52; -0.91 to -0.14); dietary fat reduction (SMD -0.21; -0.31 to -0.10); and self-efficacy (SMD 0.41; 0.21 to 0.62). For the outcome of achieving or exceeding physical activity thresholds, health coaching showed a positive trend when compared with inactive controls, but the contrast was not statistically significant (n=5; SMD 0.33; 95% CI -0.54 to 1.19). Similarly, the effect of health coaching on adherence to a prespecified dietary plan was also not significant when compared with an inactive comparator (SMD 0.05; 95% CI -0.08 to 0.19). Only change in physical activity had sufficient studies to compare effects against trials with active comparators. When compared to active controls, physical activity change was not significant (SMD 0.17; -0.32 to 0.67). Many pooled estimates exhibited moderate to high statistical heterogeneity ( $I^2 \ge 50\%$ ). In qualitative syntheses, results were mixed or inconclusive for health coaching effects on functional status, smoking, and medication adherence. However, qualitative evidence suggests that coaching has a positive effect on systolic blood pressure, cholesterol, and total calorie reduction. These trends are based on a limited number of studies, and findings are inconsistent for systolic blood pressure and cholesterol.

For KQ 2, we looked at 5 potential moderators of health coaching: study population, intervention dose operationalized as number of planned contacts, primary mode of intervention delivery, type of individual conducting the coaching intervention, and intervention concordance score. None of these factors were robust predictors of treatment effects; however, some qualitative patterns of effects emerged. While results on dose of intervention are inconclusive, there is some evidence that doses that were in the middle of the range in number of planned sessions may yield more benefit than those with smaller or larger numbers of planned sessions. Also, health coaching delivered by either telephone or in-person yielded similar small to moderate positive effects



<sup>&</sup>lt;sup>b</sup> Summary effect for the 17 trials that assessed HbA1c as a continuous variable. Abbreviations: CI=confidence interval; MD=mean difference; RCTs=randomized controlled trials; ROB=risk of bias; SOE=strength of evidence

across several outcomes. However, not all estimates were statistically significant. For the type of individual conducting the coaching intervention, the majority of analyses identified no clear pattern of effect. We did find some limited evidence from studies that reported HbA1c and physical activity outcomes that use of behavioral healthcare providers may positively influence the effect of health coaching. Likely training of personnel is a key factor in treatment effects; however, training was highly variable across studies. We were unable to explore the type or level of training as a moderator of treatment effects. Also we were not able to assess the impact of using a certified health coach because only one study reported using such personnel. Moreover, because of the nascent state of health coaching, there is no single certification standard for certifying coaches, so even this training and personnel distinction is fraught with problems.

## **CLINICAL IMPLICATIONS**

While there has been one recent review of health coaching,<sup>68</sup> ours is the first to attempt to quantitatively synthesize the evidence on health coaching for adults with chronic medical conditions. The results of our review provide important quantifiable, new information on the impact of self-identified health coaching across clinical outcomes, patient health behaviors, and self-efficacy. Overall, we found some small effects of health coaching that are both statistically significant and within acceptable ranges for clinically significant changes. For HbA1c, there is consensus that improvements of 0.3%—the summary effect found in this report—are clinically relevant changes and, as such, health coaching appears to be a clinically relevant intervention for diabetes management. However, other systematic reviews of nonpharmacologic interventions (*eg*, shared medical appointments, chronic disease self-management) have shown somewhat greater effects.<sup>69,70</sup>

Studies that assessed key cardiovascular outcomes were not amenable to quantitative syntheses. Qualitative synthesis suggests, however, that health coaching also produces small but clinically relevant changes in systolic blood pressure and cholesterol similar in magnitude to those seen for HbA1c in those studies that showed an impact (effect size range: 0.36 to 0.46 mmol/dl of cholesterol, 2.6 to 6.4 mmHg for systolic blood pressure). Yet results were inconsistent across the included trials.

Similarly, health coaching produced small, statistically significant effects on some of the prioritized health behaviors when compared with inactive controls. The 6 trials of health coaching in the pooled analysis that evaluated physical activity change as measured in metrics such as step counts or minutes of activity demonstrated improvements of 0.29 SD compared with usual care. To contextualize this, a meta-analysis of observational studies found that the pooled SD of number of steps was 2295<sup>71</sup>; thus, our results would suggest that health coaching showed an improvement equivalent to about 665 steps/day. The minimum clinically important difference in steps/day, in one study, <sup>72</sup> was about 600. This suggests that health coaching is weakly potent on physical activity. Similarly, we found that health coaching produced 0.52 decrease in BMI. While promising, this decrease in BMI likely falls short of the reductions in body weight deemed clinically significant. Reduction in calories is the most noncontroversial outcome of dietary interventions. The 2 studies that evaluated the effect of health coaching on total calories both showed benefit, at the level of ~100 kcal/day in one study, and ~500 kcal/day in the other. Reduction of caloric intake by 500 kcal/day would clearly be clinically meaningful. For selfefficacy, health coaching had a moderate impact, with a pooled SMD of 0.41. However, the association of self-efficacy with disease control has proved challenging to assess, and so the clinical relevance of this moderate change in intermediate outcome is uncertain.





Only one study actively recruited Veterans, yet all studies were conducted among populations recruited for at least one underlying chronic medical condition including obesity, diabetes, and cardiovascular disease, so our results likely apply to a broader group of Veterans. It is likely that the results of these studies are highly applicable to the VA, because these conditions are common among VA users. However, having so few studies with large sample sizes leaves unanswered questions of feasibility around integrating health coaching into a healthcare system with large, heterogeneous patient populations and multiple types of providers and number of providers.

Overall, it is likely premature to either dismiss or adopt health coaching as a strategy for producing clinically significant improvements in key clinical and health behavior outcomes. Beyond HbA1c and weight management outcomes (ie, BMI, kilograms), many comparisons were based on a small number of studies and study quality was poor or unclear across most of the included studies. Further, many pooled estimates exhibited moderate to high statistical heterogeneity ( $I^2 \ge 50\%$ ), limiting conclusions that can be drawn from these pooled estimates. The changes seen beyond usual care were similar to those seen in the literature for a number of other self-management education interventions.<sup>73</sup> Thus, our results suggest that health coaching may be an effective self-management approach. It is important to note that many of the interventions used multiple noncoaching components (eg, meal replacements, pedometers, supervised exercise sessions) as part of the overall intervention package, which makes it difficult to isolate the impact of health coaching alone. Further work is needed on how health coaching distinguishes itself from other behavioral, patient-focused approaches and when it may be the optimal behavioral approach.

## **LIMITATIONS**

Our review has a number of strengths, including a protocol-driven design, a comprehensive search, and careful quality assessment. Also, we conducted both quantitative and qualitative synthesis when possible. Our review, and the literature, have limitations. Our review was limited to English-language publications, but the likelihood of identifying relevant data unavailable from English-language sources is low. We also limited our study to RCTs only, which excluded some evidence from nonrandomized designs. The number of identified studies for many outcomes was small, and most trials had design limitations that affected study quality (51% judged to be unclear risk of bias; 34% judged as high risk of bias). It should be noted that many of the studies evaluated as unclear or high risk of bias did not provide adequate information needed to fully judge risk of bias related to key intervention design elements, including randomization, blinding, and reporting.

Many pooled estimates exhibited moderate to high statistical heterogeneity ( $I^2 \ge 50\%$ ), limiting conclusions that can be drawn from these pooled estimates. We explored if the effects of health coaching varied by intervention characteristics, including, patient chronic disease status, intervention dose (ie, the number of coaching sessions), mode of coaching delivery, individuals conducting health coaching (eg, healthcare providers, peers), and concordance of health coaching intervention with an a priori list of key elements. However, none of these individual factors was a robust predictor of heterogeneity. Thus, the observed heterogeneity is likely attributable to a combination of factors that relate to underlying differences in trial populations, comparators, interventions, inconsistency in how outcomes were measured or operationalized, and study design and quality issues. Further, many of the outcomes included in these analyses were secondary outcomes of the included trial. As such, it is important to note studies included





variability in baseline levels of secondary outcomes that ranged from normal to out-of-acceptable ranges, which likely contribute to the variability seen in treatment effects.

As there is no consensus on how to define health coaching or the elements that constitute a health coaching intervention, we included studies that self-identified primarily as coaching interventions. Thus, we included and evaluated a diversity of interventions that varied by content, theoretical orientation, approach, and other factors that may impact overall effects. Any method of identifying literature for complex behavioral interventions has strengths and limitations. This is even more pronounced when the complex behavioral intervention has not been well-defined and there is no consensus on what constitutes key elements of the approach. Health coaching is not immune to these complexities. As illustrated in Wolever's seminal 2011 *Archives of Internal Medicine* commentary, <sup>10</sup> there is currently no agreement on what comprises health coaching. To date, there has also been no research to establish the active ingredients of a health coaching intervention. Thus, in close consultation with our key stakeholders and our technical expert panel, we weighed our options for identifying this literature and jointly decided on use of self-identified interventions. This approach is supported in the literature; it has been used in at least 2 other recent systematic reviews of health coaching. <sup>9,68</sup>

We recognize that any approach to identifying this literature would introduce heterogeneity. We sought to unpack this variability and, in consultation with our content experts and stakeholders, we developed an *a priori* list of potential moderators of intervention effects to explore. Yet, the number of studies precluded any analyses of variability by more than one characteristic at a time. Thus, we sought to further explore variability in treatment effects by applying a health coaching concordance standard across the identified literature. We co-developed this concordance score with stakeholders, technical expert panel members, and local experts in health coaching. As many behavior change approaches share common elements, the key elements identified by our stakeholders were not unique to health coaching. While this exploratory concordance score was not a robust predictor of variation in treatment effects, the inconsistency in the application of these elements across the 41 included trials underscored the overall heterogeneity in the included studies.

#### RESEARCH GAPS/FUTURE RESEARCH

This comprehensive review of the literature identified several gaps in the current evidence that warrant future investigation. We used the framework recommended by Robinson et al<sup>74</sup> to identify gaps in evidence and classify why these gaps exist (Table 17). This approach considers the population, intervention, comparator, outcome, timing, and setting (PICOTS) to identify gaps and classifies them as due to (1) low strength of evidence or imprecise information, (2) biased information, (3) inconsistency or unknown consistency, and (4) not the right information. VA and other healthcare systems should consider their clinical and policy needs when deciding whether to invest in research to address gaps in evidence.

**Table 17. Evidence Gaps and Future Research** 

Evidence Gap	Reason	Type of Studies to Consider
Population	1	
<ul> <li>Limited trials that actively recruited Veterans</li> <li>Beyond diabetes and obesity, limited studies among those with other chronic medical illnesses and/or multiple chronic conditions</li> </ul>	Insufficient information	<ul><li>RCTs</li><li>Quasi-experimental studies</li><li>Prospective cohort studies</li></ul>
Interventions		
<ul> <li>What constitutes health coaching?</li> <li>What are the key elements of health coaching that impact clinical and behavioral outcomes?</li> <li>What is the optimal dose (eg, frequency and duration of sessions, length of intervention) of health coaching?</li> <li>Does coach type and coach training impact clinical and behavioral outcomes?</li> <li>Over what length of time are clinical and behavioral changes both achieved and maintained?</li> </ul>	Insufficient information	<ul> <li>Comparative effectiveness trials of different types of intervention packages</li> <li>Stepped and adaptive trial designs</li> <li>Dismantling studies</li> <li>Longitudinal studies</li> </ul>
Comparators	1	-
<ul> <li>Relatively few studies that used active comparators</li> <li>Few head-to-head comparisons of different interventionist types, doses, modalities.</li> </ul>	Insufficient information	RCTs     Comparative effectiveness trials
Outcomes	1	
Uncertain effects on:     Patient satisfaction with healthcare     Healthcare utilization     Quality of life Limited information on:     Smoking     Physical function     Aspects of health diets (eg, total calories, fats)     Systolic blood pressure     Cholesterol     Maintenance of effects over time Exploration of impact on newer constructs such as patient activation.	Insufficient information	RCTs     Prospective cohort studies     Non-randomized controlled before-and-after studies     Secondary analyses of existing trial data
Setting		
Limited setting from VA Healthcare System or other large healthcare systems  Abbreviation: PCTs=rendemized controlled triels	Insufficient information	<ul> <li>RCTs</li> <li>Hybrid implementation designs</li> <li>Prospective or retrospective cohort studies</li> <li>Nonrandomized controlled before-and-after studies</li> </ul>

Abbreviation: RCTs=randomized controlled trials



#### CONCLUSIONS

Overall results suggest that self-identified health coaching interventions have the potential to produce small positive, statistically significant effects on HbA1c decreases, BMI reductions, physical activity increases, dietary fat reductions, and self-efficacy improvements when compared with inactive controls. This trend did not extend to studies with more robust comparators. We also saw a small positive, qualitative trend toward impact on total calorie reductions; however, we found only 2 studies that assessed this outcome. Some of these findings may result in effects that cross the clinically significant threshold. However, the relatively large number of studies at high or unclear risk of bias and the moderate to high heterogeneity in pooled estimates limit certainty about the interpretation of our findings and the conclusions that may be drawn.

None of the moderators were strong drivers of variability in treatment effects, suggesting that moderate to high heterogeneity in pooled estimates may be driven by a combination of intervention characteristics. We allowed studies to self-identify as health coaching interventions. Thus, variability in what is considered health coaching may contribute to the overall inconsistency and heterogeneity of effects. While health coaching may be a promising intervention modality, additional research is warranted on the impact of health coaching, especially in areas with limited identified literature (*eg*, medication adherence, smoking, physical function). Compared with usual care, our results suggest that health coaching may be an effective self-management approach; however, variability in the included studies, lack of consistency in what constitutes health coaching, and inclusion of multiple noncoaching components as part of the overall intervention package makes it difficult to draw firm conclusions on the impact of health coaching alone. Further, it is unclear whether health coaching offers additional advantages over other behavioral intervention modalities or when compared with more robust and active comparators. Thus, it may be premature to either dismiss or adopt health coaching in clinical or community-based settings.

Prior to conducting additional studies evaluating the effectiveness of health coaching, some foundational steps should be considered. First, both clinical and research fields would benefit from a consensus definition of health coaching. Next, training and/or credentialing required to become a certified health coach should be codified. Third, more stringent application of publication guidelines requiring full descriptions of study procedures, including randomization, blinding, and analytic methods, would allow for greater transparency and evaluation around risk of bias of complex behavioral interventions. Together, these steps would promote greater consistency in health coaching interventions, allow for more direct comparisons across studies, and promote more accurate evaluation of risk of bias. Finally, future studies should employ innovative and rigorous designs (refer to Table 17) to explore the central elements that distinguish health coaching from other behavior change and health promotion interventions and examine how these unique elements impact clinical and behavioral outcomes. Health coaching is an emerging field with shifting definitions across time. Our approach in this evidence review offers a snapshot of the literature at this time. The heterogeneity of the identified studies we included underscores the importance of better efforts to distinguish this approach from other common behavioral interventions.



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# **APPENDIX A. SEARCH STRATEGY**

# PubMed: 12/14/2015

Set	Terms	Results
1	"Wellness coach"[tiab] OR "wellness coaching"[tiab] OR "health coach"[tiab] OR	389
	"health coaching"[tiab] OR "peer coach"[tiab] OR "peer coaching"[tiab]	
2	coaching[tiab] OR coach[tiab]	4710
3	"Health Education" [Mesh] OR "Health Promotion" [Mesh] OR "Motivational Interviewing" [Mesh] OR "Health Behavior" [Mesh] OR "Health Knowledge, Attitudes, Practice" [Mesh] OR "Counseling" [Mesh] OR "Peer Group" [Mesh] OR "Social Support" [Mesh] OR "Self Care" [Mesh] OR "Patient Education as Topic" [Mesh] OR "Exercise" [Mesh] OR "Exercise Therapy" [Mesh] OR "Weight Loss" [Mesh] OR "Nutrition Therapy" [Mesh] OR "Chronic Disease/prevention and control" [Mesh] OR "Chronic Disease/rehabilitation" [Mesh] OR "health education" [tiab] OR "patient education" [tiab] OR "motivational interviewing" [tiab] OR attitudes [tiab] OR attitude [tiab] OR counseling [tiab] OR "social support" [tiab] OR "psychosocial support" [tiab] OR "self care" [tiab] OR "self-efficacy" [tiab] OR "self management" [tiab] OR "physical activity" [tiab] OR "weight loss" [tiab] OR exercise [tiab] OR fitness [tiab] OR nutrition [tiab]	1153106
4	#2 AND #3	
5	#1 OR #4	2119
6	(randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR "Comparative Study"[Publication Type] OR "Controlled Clinical Trial"[Publication Type] OR Nonrandom[tiab] OR nonrandom[tiab] OR nonrandomized[tiab] OR non-randomized[tiab] OR nonrandomized[tiab] OR "pre-post"[tiab] OR "post-test"[tiab] OR "post test"[tiab] OR pre-test[tiab] OR "pre-test[tiab] OR "pre-test"[tiab] OR quasi-experiment*[tiab] OR quasirandom*[tiab] OR	2902653
	quasi-random*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab] OR (controlled[tiab] AND (trial[tiab] OR study[tiab]))) NOT (animals[mh] NOT humans[mh]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR	
7	quasi-random*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab] OR (controlled[tiab] AND (trial[tiab] OR study[tiab]))) NOT (animals[mh] NOT	927

# Embase: 12/14/2015

Set	Terms	Results
1	'Wellness coach':ti,ab OR 'wellness coaching':ti,ab OR 'health coach':ti,ab OR	494
	'health coaching':ti,ab OR 'peer coach':ti,ab OR 'peer coaching':ti,ab	
2	Coaching:ti,ab OR coach:ti,ab	6298
3	'health education'/exp OR 'health promotion'/exp OR 'motivational interviewing'/exp OR 'health behavior'/exp OR 'attitude to health'/exp OR 'counseling'/exp OR 'peer group'/exp OR 'social support'/exp OR 'self care'/exp OR 'patient education'/exp OR 'exercise'/exp OR 'kinesiotherapy'/exp OR 'weight reduction'/exp OR 'diet therapy'/exp OR 'chronic disease'/exp/dm_rh,dm_dm,dm_pc OR 'health education':ti,ab OR 'patient education':ti,ab OR 'motivational interviewing':ti,ab OR attitudes:ti,ab OR attitude:ti,ab OR counseling:ti,ab OR 'social support':ti,ab OR 'psychosocial support':ti,ab OR 'self care':ti,ab OR 'self-efficacy':ti,ab OR 'self management':ti,ab OR 'physical activity':ti,ab OR 'weight loss':ti,ab OR exercise:ti,ab OR fitness:ti,ab OR nutrition:ti,ab	1754744
4	#2 AND #3	2946
5	#1 OR #4	3048

Set	Terms	Results
6	'randomized controlled trial'/exp OR 'crossover procedure'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR random*:ti,ab OR factorial*:ti,ab OR crossover*:ti,ab OR (cross NEAR/1 over*):ti,ab OR placebo*:ti,ab OR (doubl* NEAR/1 blind*):ti,ab OR (singl* NEAR/1 blind*):ti,ab OR assign*:ti,ab OR allocat*:ti,ab OR volunteer*:ti,ab OR 'clinical study'/exp OR 'clinical trial':ti,ab OR 'clinical trials':ti,ab OR 'controlled study'/exp OR (controlled:ti,ab AND (trial:ti,ab OR study:ti,ab)) OR (non NEAR/1 random*):ti,ab OR (quasi NEAR/1 experiment*):ti,ab OR (quasi NEAR/1 random*):ti,ab OR (quasi NEAR/1 control*):ti,ab OR 'comparative effectiveness'/exp OR 'comparative study'/exp OR 'comparative study':ti,ab OR 'pre-post':ti,ab OR 'post test':ti,ab OR pretest:ti,ab OR pre-test:ti,ab OR 'pre test':ti,ab OR quasiexperiment*:ti,ab OR quasirandom*:ti,ab OR quasicontrol*:ti,ab NOT ('case report'/exp OR 'case study'/exp OR 'editorial'/exp OR 'letter'/exp OR 'note'/exp) AND [humans]/lim	6095040
7	#5 AND #6	1388
8	[embase]/lim NOT [medline]/lim	
9	#7 AND #8	560
10	#9 limit to 2000 – present	552

# CINAHL: 12/14/2015

CITYI	HL. 12/14/2015	
Set	Terms	Results
1	TI ("Wellness coach" OR "wellness coaching" OR "health coach" OR "health coaching" OR "peer coach" OR "peer coaching") OR AB ("Wellness coach" OR "wellness coaching" OR "health coach" OR "health coaching" OR "peer coach" OR	305
	"peer coaching")	
2	TI (coaching OR coach) OR AB (coaching OR coach)	4864
3	(MH "Health Education+") OR (MH "Health Promotion+") OR (MH "Motivational Interviewing") OR (MH "Health Behavior+") OR (MH "Attitude to Health+") OR (MH "Health Knowledge") OR (MH "Counseling+") OR (MH "Peer Group") OR (MH "Support, Psychosocial+") OR (MH "Social Environment+") OR (MH "Self Care+") OR (MH "Patient Education+") OR (MH "Exercise+") OR (MH "Therapeutic Exercise+") OR (MH "Weight Loss+") OR (MH "Diet Therapy+") OR (MH "Chronic Disease/PC") OR (MH "Chronic Disease/RH") OR TI ("health education" OR "patient education" OR "motivational interviewing" OR attitudes OR attitude OR counseling OR "social support" OR "psychosocial support" OR "self care" OR "selfefficacy" OR "self management" OR "physical activity" OR "weight loss" OR exercise OR fitness OR nutrition) OR AB ("health education" OR "patient education" OR "motivational interviewing" OR attitudes OR attitude OR counseling OR "social support" OR "psychosocial support" OR "self-efficacy" OR "self management" OR "physical activity" OR "self-efficacy" OR "self management" OR "physical activity" OR "weight loss" OR exercise OR fitness OR nutrition)	612054
4	#2 AND #3	2379
5	#1 OR #4	2438



Set	Terms	Results
6	(MH "Clinical Trials+") OR PT Clinical trial OR PT randomized controlled trial OR TX clinic* n1 trial* OR TX ( (singl* n1 blind*) OR (singl* n1 mask*) ) OR TX ( (doubl* n1 blind*) OR (doubl* n1 mask*) ) OR TX ( (tripl* n1 blind*) OR (tripl* n1 mask*) ) OR TX ( (trebl* n1 blind*) OR (trebl* n1 mask*) ) OR (MH "Random Assignment") OR (MH "Quantitative Studies") OR TI (randomized OR randomised OR randomization OR randomisation OR randomisation OR randomised OR randomization OR randomised OR randomization OR randomised OR non-randomized OR nonrandomized OR non-randomized OR nonrandomized OR (MH "Comparative Studies") OR (MH "Quasi-Experimental Studies+") OR TI ("prepost" OR "post-test" OR "post test" OR pretest OR pre-test OR "pre test" OR quasi-control* OR quasicontrol* OR (controlled AND (trial OR study))) OR AB ("pre-post" OR "post-test" OR "post test" OR pretest OR pre-test OR "pre test" OR quasi-experiment* OR quasicontrol* OR (controlled AND (trial OR study))) NOT (PT editorial OR PT letter OR PT case study OR PT commentary)	1371759
8	#5 AND #6	1288
8	#7 limit to 2000 – present	1239

# PsycINFO: 12/14/2015

Set	Terms	Results
1	TI ( "wellness coach" OR "wellness coaching" OR "health coach" OR "health coaching" OR "peer coach" OR "peer coaching" ) OR AB ( "wellness coach" OR "wellness coaching" OR "health coach" OR "health coaching" OR "peer coach" OR "peer coaching" )	303
2	TI (coaching OR coach) OR AB (coaching OR coach)	11927
3	DE "Health Education" OR DE "Health Promotion" OR DE "Motivational Interviewing" OR DE "Health Behavior" OR DE "Health Knowledge" OR DE "Health Attitudes" OR DE "Counseling" OR SU counseling OR DE "Peer Relations" OR DE "Peer Pressure" OR DE "Peers" OR DE "Social Support" OR DE "Support Groups" OR DE "Self-Care Skills" OR DE "Client Education" OR DE "Exercise" OR DE "Aerobic Exercise" OR DE "Weight lifting" OR DE "Yoga" OR DE "Movement Therapy" OR DE "Weight Loss" OR DE "Diets" OR TI ("health education" OR "patient education" OR "motivational interviewing" OR attitudes OR attitude OR counseling OR "social support" OR "psychosocial support" OR "self care" OR "selfefficacy" OR "self management" OR "physical activity" OR "weight loss" OR exercise OR fitness OR nutrition) OR AB ("health education" OR "patient education" OR "motivational interviewing" OR attitudes OR attitude OR counseling OR "social support" OR "psychosocial support" OR "self-efficacy" OR "self management" OR "physical activity" OR "self-efficacy" OR "self management" OR "physical activity" OR "weight loss" OR exercise OR fitness OR nutrition)	472340
4	#2 AND #3	2605
5	#1 OR #4	2739

Set	Terms	Results
6	ZC "treatment outcome/clinical trial"OR DE "Clinical Trials" OR TI (randomized OR randomised OR randomization OR randomisation OR randomised OR trial OR trials OR groups) OR AB (randomized OR randomised OR randomization OR randomisation OR randomiy OR trial OR trials OR groups) OR TI ("comparative study") OR AB ("comparative study") OR TI (Nonrandom OR non-random OR nonrandomized OR non-randomized OR nonrandomized OR non-randomised OR "pre-post" OR "post-test" OR "post test" OR pretest OR pre-test OR "pre test" OR quasi-experiment* OR quasiexperiment* OR quasirandom* OR quasi-random* OR quasi-control* OR quasicontrol* OR (controlled AND (trial OR study)))) OR AB (Nonrandom OR non-randomised OR "pre-post" OR "post-test" OR "post test" OR pretest OR pre-test OR "pre test" OR quasi-experiment* OR quasiexperiment* OR quasirandom* OR quasi-random* OR quasi-control* OR quasicontrol* OR (controlled AND (trial OR study)))) AND (ZZ "journal article")	877890
7	#5 AND #6	893
8	#7 limit to 2000 – present; limit to human	784

# **APPENDIX B. STUDY CHARACTERISTICS TABLE**

For full study citations, please refer to the report's main reference list.

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Annesi, 2011 <sup>22</sup> USA No	Obesity Community 6 months	Six 1-hour individual meetings with YMCA "Coach Approach" trained wellness specialist + at-home exercise prescription (3/week for 24 weeks for total of 72 sessions)  Goal-setting, self-monitoring, and chronic disease education	Social cognitive theory Self-efficacy (Bandura)	6 individual meetings with standard- trained fitness specialist + 72 at-home exercise sessions  Problem-solving, structured, supervised exercise, chronic disease education	Self-efficacy	High YMCA
Appel, 2011 <sup>23</sup> USA No	Obesity Primary care  96 weeks (everyone had inperson baseline and end-of-treatment measures)	Coaching in-person (group/individual) weekly for first 12 weeks, monthly (group/individual) next 12 weeks, then either in-person or phone for last 72 weeks by trained, supervised health professional + website and email  Goal-setting, self-monitoring, problem-solving, chronic disease education, and "learning modules online"	Social cognitive theory  Behavioral self- management  Motivational interviewing	(1) Coaching support delivered remotely by phone, study-specific website, and email (2) Self-directed weight loss using website (baseline and 96-week follow-up)	Weight change BMI	Unclear NIH: NHLBI
Blackberry, 2013 <sup>24</sup> Australia No	Type 2 diabetes Primary care 18 months	1 in-person baseline assessment, then 8 structured phone sessions on self-management of diabetes with coaching by trained, supervised general practice nurse; written session summaries provided to patient and primary care physician  Self-monitoring and "coaching on patient-provider communication"	NR NR	After 1 in-person baseline assessment, usual care was provided including referrals to dieticians and other diabetes specialists	A1c Weight change Self-efficacy	Low  Australian National Health and Medical Research Council

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Bostrom, 2016 <sup>25</sup> Sweden No	Systemic lupus erythematosus  Rheumatology clinic  12 months	(1) 0-3 months: Individual, in-person 1-hour coaching by physiotherapist at study start, 6 weeks, and 12 weeks; general education, supervised aerobic exercise, loan and use of heart rate monitor, and use of physical activity diary (2) 4-12 months: Some physical activity supervision, heart rate monitor, and diary  None	Social cognitive theory  Behavior theory model	Usual care at rheumatology clinic, but patients in control group were asked not to change their activity level during the study	Physical activity	Low Swedish Rheumatism Association and Vardal Foundation, Karolinska (Univ) Institute
Brodin, 2008 <sup>26</sup> Sweden No	Rheumatoid arthritis  Rheumatology clinics  12 months	Phone support after 1 week, moving to once monthly by physical therapist coach; physical function tests every 3 months to encourage adherence to graded activity goals, feedback given  Goal-setting, problem-solving, chronic disease education	Cognitive behavioral therapy NR	Usual care (no description given other than "control group")	Physical activity	High Government, Swedish Research Council, the Vardal Foundation, the Swedish Rheumatism Association
Browning, 2014 <sup>27</sup> China No	Type 2 diabetes  Community Health Center  12 months	Heath coaching by nurse via in- person + phone (both 2/month for first 3 months) diminishing over next 9 months; maximum contact was 19 phone and 18 in-person sessions Not reported	Transtheoretical model/ stages of change  Motivational interviewing	Usual care provided by family physician where patients were typically referred to diabetes specialists or to Traditional Chinese Medicine practitioners	A1c BMI	Unclear Government and private foundation
Cinar, 2014 <sup>28</sup> Turkey No	Type 2 diabetes  Hospital clinics  13 months	In addition to standard health education, 2 in-person individual visits + single 10- to 20-minute phone call within first 3 weeks; 1 in-person + 1 call in next 6 months; 1 in-person + 1 call in last 6 months, for up to 7 total contacts with the behavioral health specialist coach  Self-monitoring, chronic disease education	NR NR	Health education consisting of 3 seminars on oral health and diabetes management	A1c	Unclear  Government, International Research Fund

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Damschroder, 2014 <sup>29</sup> USA Yes	Obesity  VA medical centers  12 months	ASPIRE-Group: Coaching via inperson 90-minute group sessions with a specially trained lifestyle coach for 1/week for 3 months, then 2/month for 6 months, then 60-minute sessions 1/month for last 3 months  Goal-setting, self-monitoring, problem-solving, chronic disease education	Unclear  Problem-solving therapy	(1) ASPIRE-Phone: Coaching via phone for 30 minutes, 1 time/week for 3 months, then 20 minutes for remaining time (2 times/month for 6 months decreasing to 1 time/month for last 3 months) (2) Standard VA MOVE! program	Weight change BMI Physical activity Diet	High VA
Frosch, 2011 <sup>21</sup> USA No	Type 2 diabetes Primary care Duration NR	Phone coaching by trained nurse diabetes educator, 5 sessions total: first session for 60 minutes; sessions 2-3 for 30 minutes, sessions 4-5 for 15 minutes  Goal-setting, self-monitoring, problem-solving, chronic disease education	NR Motivational interviewing	Education brochure on diabetes management; no other strategies employed	A1c  BMI  Physical activity  Diet  Medication adherence	Unclear  NIA/NIH, private foundation
Glasgow, 2003 <sup>30</sup> USA No	Type 2 diabetes Primary care 10 month (40 weeks)	Internet-based basic information + either (1) tailored self-management (computer-mediated access to trained professional coach approximately twice weekly or (2) peer support via online forum and newsletters  Goal-setting, self-monitoring, chronic disease education	Self-efficacy theory NR	In-home training to use website providing chronic disease education without additional support	A1c Physical activity Diet	High NIH: NIDDK
Hawkes, 2013 <sup>31</sup> Australia No	Colorectal cancer Cancer registry 6 months	11 health coaching sessions biweekly for 5 months via phone by nurse, behavioral specialist, or health educator (average duration of call, 31.5 minutes) + handbook + motivational postcards + pedometer  Goal-setting, self-monitoring, chronic disease education	NR Acceptance and commitment therapy	Usual care + educational brochures on understanding colorectal cancer, cutting cancer risk, diet, and physical activity + quarterly mailed educational newsletter	BMI Physical activity Diet Smoking	Australian government (cancer division of health branch)

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Holland, 2005 <sup>32</sup> USA No	Mixed: at least one chronic condition; unspecified  Community  12 months	In-person meeting with nurse at baseline and 6 months, minimum 4 health coaching calls in between, 12 monthly newsletters, fitness program  Goal-setting, chronic disease education, counseling with MSW, if depressed	NR NR	Usual care; controls were not recontacted by the program until the anniversary date of their initial interview for follow-up	BMI Physical activity	Unclear Private foundation
Karhula, 2015 <sup>33</sup> Finland No	Mixed population (type 2 diabetes and CVD)  Community integrative care  12 months	One coaching phone call from employee trained in Pfizer coaching model every 4-6 weeks (target=12 total); length of call approximately 30 minutes and emphasized problemsolving skills + monitoring of weight, blood glucose, SBP, and/or step count dependent on diagnosis via mobile application  Problem-solving, self-monitoring	Wagner's chronic care Pfizer's health coaching model	Usual care; no further details or description of control group given	A1c (diabetes only)  Weight (diabetes and CVD separately)	Unclear  Government, European Commission, Industry
Kim, 2015 <sup>34</sup> USA No	Type 2 Diabetes  Community  13-14 months	Six 2-hour group sessions over 6 weeks, then monthly coaching calls for 1 year from trained nurses or community health workers; calls ranged 15-45 minutes  Goal-setting, self-monitoring, problem-solving, chronic disease education	Precede-Proceed  Motivational interviewing, problem-solving therapy	Waitlist; no further details given other than control was oversampled to assure adequate retention	A1c Self-efficacy	High NIH: NIDDK
Knittle, 2015 <sup>35</sup> Netherlands No	Rheumatoid arthritis Specialty clinics 18 weeks	2 in-person, individual coaching sessions with rheumatology nurse, 40-60 minutes, at weeks 4 and 5; 3 followup phone calls, 20 minutes, weeks 6, 12, and 18  Goal-setting, self-monitoring, problem-solving, chronic disease education	Health Belief Model, self-regulation theory  Motivational interviewing, problem- solving therapy, self- regulation theory	Education via 1 in-person group session with nurse	Physical activity Self-efficacy Functional status	Unclear Private foundation

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Lin, 2013 <sup>16</sup> USA No	Hypertension Primary care  18 months total (5 months group intervention)	Weekly small groups for 20 weeks with trained health educators and dieticians + manual; strategies to manage weight and blood pressure via DASH diet, increase exercise; and coaching strategies; during and after group intervention, a peer educator phoned participants monthly for a total of 18 calls  Goal-setting, self-monitoring, problem-solving, chronic disease education	Transtheoretical Model / Stages of Change; Social-Cognitive Theory  Motivational interviewing, problem- solving therapy	Usual care was an individual visit with interventionist to receive advice + written materials on lifestyle modification for blood pressure control consistent with JNC-7 guidelines	SBP Diet	Low
Luley, 2014 <sup>36</sup> Germany No	Metabolic syndrome  Community setting  12 months	1 basic education session + monthly health coaching call from trained physician or nurse, each approximately 20 minutes + accelerometer (data transmitted to coach as basis for phone calls)  None reported	NR NR	After 1 basic education session that included an explanation of importance of physical activity and diet, patients were randomized, then control group left	ВМІ	High  German Federal Ministry of Education and Research
Ma, 2013 <sup>37</sup> (Companion study, Azar, 2013 <sup>38</sup> ) USA	Obesity Primary care 15 months (60 weeks)	Lifestyle Balance of 2 weekly, inperson group sessions (90-120 minutes) using goal-setting, with food tastings and 30-45 minutes of guided exercise led by coach-dietician followed by 12-month maintenance phase; personalized email from coach monthly  Goal-setting, self-monitoring, problem-solving, chronic disease education, structured exercise, relapse prevention	NR NR	(1) Self-led via DVD and email correspondence with coach/RD that used goal-setting, self-monitoring, and chronic disease education (2) Usual care; no further details given	Weight BMI	Low  NIH: NIDDK, private foundation

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
McMurray, 2002 <sup>39</sup> USA No	End stage renal disease + diabetes Dialysis unit 1 year (52 weeks)	Minimum of monthly (for peritoneal patients) in-person, individual sessions with diabetes care manager for motivational coaching; weekly contact as needed by phone with manager, social worker, registered dietician, or registered nurse to cover self-management and diabetes care; maximum of 3 times/week (for hemodialysis patients)  Problem-solving	NR NR	Usual care at a standard dialysis unit	A1c	Unclear National Kidney Foundation
Nishita, 2013 <sup>40</sup> USA No  Patja, 2012 <sup>41</sup> Finland No	Type 2 diabetes  Community workplace setting  12 months  Mixed: Type 2 diabetes, CVD, CHF  Primary care and hospital	Average of ten 1-hour in-person, individual sessions with certified health coach and four 45-minute sessions with pharmacist over intervention year  Goal-setting, self-monitoring, problem-solving, chronic disease education  Monthly phone calls with nurse coach (initial duration averaging 60 minutes, decreasing to 30 minutes over time); call completion averaged 10-11 calls over year; optional followup calls were rarely utilized	Health belief model, self-determination theory  Motivational interviewing, problemsolving therapy  Self-regulation theory  Motivational interviewing	Usual care; no further details given  Usual care; article states "control arm" and, with no other details given, usual care is assumed because of recruitment sites used	A1c BMI Self-efficacy  A1c (diabetes only) SBP (CVD only)	Unclear  Centers for Medicare and Medicaid Services  High  Government: Finland Innovation Fund, industry
Pearson, 2013 <sup>19</sup> (Companion study, Pearson	12 months Obesity University	Goal-setting, self-monitoring, chronic disease education  Phone coaching sessions with certified health coach 1 time/week for 12 weeks; average length of call was	NR Motivational	Scripted education-based phone lessons using cognitive behavioral therapy principles	Weight change	High Social
2012 <sup>42</sup> ) Canada No	12 weeks	45 minutes  Goal-setting, problem-solving	Interviewing and CBT	from LEARN manual 1/week for 12 weeks; average length of call was 30-45 minutes  Goal-setting, self-monitoring, problem-solving, social support and chronic disease management		Sciences and Humanities Research Council of Canada

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Pinto, 2015 <sup>43</sup> USA No	Breast cancer  Community, private practices and hospitals  12 weeks	Health coaching by peer educator via phone 1/week for 12 weeks; average call length was 18 minutes + pedometer + heart rate monitor + physical activity tipsheets  Goal-setting, self-monitoring, problem-solving, chronic disease education	Transtheoretical model/ stages of change, social cognitive theory	Attention control: phone contact with peer educator 1/week for 12 weeks, but topics centered on breast cancer, not physical activity	Physical activity	High NIH
Ruggiero, 2010 <sup>44</sup> USA No	Type 2 diabetes Primary care 6 months	2 in-person, individual contacts (<30 minutes) with certified medical assistant trained in diabetes self-care coaching at baseline and 3 months + 4 monthly phone contacts (<15 minutes) in between clinic visits  Goal-setting, self-monitoring, problem-solving, chronic disease education	Transtheoretical model NR	Usual care with physician + basic diabetes education handbook developed by health system staff	A1c	Unclear NIA, NIH
Ruggiero, 2014 <sup>20</sup> USA No	Type 2 diabetes Primary care 12 months	Quarterly in-person, individual coaching sessions with specially trained certified medical assistants for 30 minutes at clinic appointments; up to 8 monthly phone calls, 15 minutes, between in-person contacts  Goal-setting, self-monitoring, chronic disease education	Transtheoretical model/ stages of change, empowerment theory  Motivational interviewing	Enhanced treatment as usual; quarterly physician check-ups; referrals to specialty care (eg, podiatrist, endocrinologist) when necessary; basic education provided by "Diabetes: You're in Control" educational booklet	A1c Diet Physical Activity	High NIH
Sacco, 2009 <sup>45</sup> USA No	Type 2 diabetes Primary care 6 months	Coaching call weekly for 3 months (from supervised psychology undergraduate), then every other week for 3 months; average duration of initial call was 54 minutes decreasing to 15-20 minutes  Goal-setting, self-monitoring, problem-solving	Social cognitive theory Problem-solving therapy	Control group received treatment as usual from a board-certified endocrinologist	A1c Physical activity Diet Self-efficacy	Unclear Private foundation

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Safford, 2015 <sup>46</sup> USA No	Type 2 diabetes Primary care 40 weeks	1-hour group diabetes education class + one 5-10 minute individual counseling session to go over baseline "diabetes report cards," then peer coaches phoned weekly for the first 2 months and at least monthly for the next 8 months  Goal-setting, self-monitoring, chronic disease education	Health belief model, social cognitive theory and chronic care model NR	1-hour group diabetes education class + 5-10 minute counseling session on a "diabetes report card" showing baseline labs at enrollment	A1c BMI	High  American  Academy of  Family  Physicians
Sandroff, 2014 <sup>47</sup> USA No	Multiple sclerosis  National registry and databases from previous studies over past 5 years  6 months	Coaching (discipline of coach not reported) via internet and 15, one-on-one video sessions (eg, Skype) for 6 months decreasing in frequency over time (from weekly to monthly)  Goal-setting, self-monitoring, problem-solving	Social cognitive theory NR	Waitlist	Physical Activity Functional status	High  National Multiple Sclerosis Society
Sherwood, 2010 <sup>48</sup> USA No	Obesity Community and university 20 weeks	DIAL: 2 active arms (same intervention for different durations: 10 sessions or 20 sessions) providing weekly telephone calls with coach (discipline not reported) lasting about 10-20 minutes + pedometer + logbook; calls followed a prescribed sequence in study manual adapted to fit into 10 or 20 lessons  None reported	NR NR	Self-directed program participants were sent copy of manual, pedometer, and logbook but were not recontacted until time for follow-up measures	Weight change (kg) Physical activity	High Government grant
Thom, 2013 <sup>49</sup> (Companion study, Moskowitz, 2103 <sup>50</sup> ) USA	Type 2 diabetes Primary care 6 months (26 weeks)	12-14 sessions of coaching by a peer educator (individual or phone at discretion of subject) with goals of phone contact at least twice/month and 2 or more in-person contacts over 6 months  Goal-setting, self-monitoring	NR NR	Usual care included all services normally available, including a nutritionist and diabetes educator via referral from their primary care physician	A1c BMI	unclear  Private foundation

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Turner, 2012 <sup>51</sup> USA No	Hypertension Primary care 6 months (26 weeks)	Phone calls every other month at 1, 3, and 5 months (duration not reported); on alternate months (2 and 4), office-based, in-person, individual counseling sessions (15-30 minutes each) with a peer educator as coach  Goal-setting, self-monitoring, problem-solving	Theory of planned behavior  Motivational interviewing, problemsolving therapy	Usual care at urban academic general medicine practices	SBP 4-year Framingham Score	Low Private foundation
Vale, 2002 <sup>52</sup> Australia No	CAD/CVD  NR (most likely cardiology)  6 months (24 weeks)	5 coaching phone calls from dietician, with first call within 2 weeks of randomization; then 3 calls, one every 6 weeks; the fifth call at 24 weeks (to schedule the 6-month assessment); duration of calls varied  Self-monitoring, chronic disease education	NR NR	Usual care; no further details given	Total cholesterol	Unclear
Vale, 2003 <sup>53</sup> Australia No	CAD/CVD  Specialist clinic: cardiology  6 months	5 coaching phone calls from nurse or dietician, with first call within 2 weeks of randomization; then 3 calls, one every 6 weeks; the fifth call at 24 weeks (to schedule the 6-month assessment); duration of calls varied Self-monitoring, chronic disease education	NR NR	Usual care; no further details given	SBP Weight change BMI Diet Smoking	Low  Private foundation, industry
Van der Wulp, 2012 <sup>54</sup> Netherlands No	Type 2 diabetes Primary care 3 months	3 in-person, individual health coaching sessions, monthly, with trained peer educator using goal-setting; duration of session not reported  Goal-setting	Social cognitive theory  Motivational interviewing	Usual care from general practitioner based on the Dutch guidelines for type 2 diabetes	Self-efficacy Physical activity	Unclear Private foundation
Varney, 2014 <sup>55</sup> Australia No	Type 2 diabetes Diabetes clinic 6 months	Initial coaching call within 2 weeks of randomization followed by at least monthly phone calls (range 4-9 sessions) from dietician coach; duration average 45 minutes initially, then 20 minutes for follow-up calls  Goal-setting, self-monitoring, problem-solving	NR Problem-solving therapy	Control group accessed usual care services, including a diabetes clinic staffed by endocrinologists, diabetes educators, and dietitians; patients typically attend the clinic at least monthly, with general practitioner visits occurring as needed	A1c Weight (kg) BMI Physical activity	High Private foundation



Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Wadden, 2011 <sup>56</sup> USA No	Obesity Primary care 24 months (104 weeks)	(1) Coaching only: primary care visits plus 10-15 minute in-person, individual coaching sessions; 2 during the first month, then monthly for 11 months with a trained medical assistant; in months 13-24, coaching could be done by phone every other month (2) Enhanced coaching: as above + choice of meal replacements or weight loss medication  Goal-setting, self-monitoring	NR NR	Usual care consisting of quarterly PCP visits that included education about weight management for 5-7 minutes each visit	BMI Weight loss	Unclear NIH: NHLBI
Wayne, 2015 <sup>57</sup> Canada No	Type 2 Diabetes Primary care 6 months (26 weeks)	Weekly health coach sessions + exercise education program with smartphone wellness mobile application; components included support for health goals and goal achievement; self-monitoring; discussion of meals, exercise, blood glucose and mood; duration of session 37 (±22) minutes/week; also health coach co-monitored patient's input to mobile application  Goal-setting, self-monitoring, structured exercise	NR NR	Weekly health coach sessions + exercise education program without smartphone application; components included support for health goals and goal achievement; self-monitoring; discussion of meals, exercise, blood glucose, and mood; session duration 39 (±28) minutes/week	A1c BMI Weight (kg)	Unclear Government
Whittemore, 2004 <sup>58</sup> USA No	Type 2 Diabetes  Outpatient diabetes education center  6 months	6 in-person, individual coaching sessions with a trained nurse: first 3 every 2 weeks; then 2 monthly; last session 3 months after first 5 sessions with phone contacts in between sessions 5 and 6  Goal-setting, self-monitoring, problem-solving, chronic disease education	NR Problem-solving therapy	Standard diabetes care, defined as regular visits with a primary care physician at approximately 3- to 4-month intervals; all women randomized to the control condition were invited to participate in the nurse-coaching intervention at the end of the study	A1c BMI Diet Physical Activity	High NIH: NINR

Study Country Veteran?	Condition Setting Duration	Intervention Strategies Used	Theoretical Orientation Therapeutic Model	Comparator	Outcomes Abstracted	Risk of Bias Funding Source
Willard-Grace, 2015 <sup>59</sup> (Companion study, Thom, 2015 <sup>60</sup> )	Mixed: diabetes, hypertension, elevated lipids  Primary care  12 months	5 in-person, individual coaching sessions at baseline, 3, 6, 9, and 12 months with a trained medical assistant as well as monthly follow-ups by phone; total 16 sessions  Goal-setting, self-monitoring	NR NR	Patients randomized to usual care had access to any resources available at the clinic, including visits with their clinician, diabetes educators, nutritionists, chronic care nurses, and educational classes	A1c SBP LDL Medication adherence	Unclear Private foundation
No Wolever, 2010 <sup>61</sup> USA No	Type 2 diabetes  Community & registry  22 weeks (5-6 months)	8 calls weekly for first 2 months, then 4 calls biweekly for 2 months; final call 1 month later for total of 14, 30-minute sessions with a trained social worker or medical assistant in psychology coach  Goal-setting, problem-solving, chronic disease education	NR Motivational interviewing, mindfulness	Usual care; randomized to the control group received no materials or correspondence during the 6-month period	A1c  Medication adherence  Physical activity	Unclear
Young, 2014 <sup>62</sup> USA No	Type 2 Diabetes  Primary care and community  Timing unclear: 9-18 weeks	1 in-person, individual session with a nurse coach followed by 5 health coaching sessions via phone or video-conferencing, about once every 2 weeks; average duration of sessions was 30 minutes  Goal-setting, self-monitoring	NR Motivational interviewing	Usual care consisted of the services and care available at the rural clinic where the participant received healthcare	Self-efficacy	Unclear NIH: NIDDK, NCATS

Abbreviations: ANCOVA=analysis of covariance, ANOVA=analysis of variance, BMI=body mass index, CI=confidence interval, A1c=glycosylated hemoglobin, JNC=Joint National Committee on Prevention, LDL=low-density lipoprotein-cholesterol., MD=mean difference, MI-via-CALC=Motivational Interview via Co-Active Life Coaching, NCATS=National Center for Advancing Translational Sciences, NHLBI=National Heart, Lung, and Blood Institute, NIDDK=National Institute for Diabetes and Digestive and Kidney Diseases, NIH=National Institutes of Health, NINR=National Institute of Nursing Research, NR=not reported, SBP=systolic blood pressure, SE=standard error, SMD=standardized mean difference

# APPENDIX C. STUDY QUALITY ASSESSMENT

#### RANDOMIZED CONTROLLED TRIALS

Detailed guidance on assessing the risk of bias is found in Higgins J, Altman DG. Chapter 8: Assessing risk of bias in included studies. In Cochrane Handbook for Systematic Reviews of Interventions Version 5.0, 2008. Available at:

http://handbook.cochrane.org/chapter 8/8 assessing risk of bias in included studies.htm.

General instructions: Rate each risk of bias item listed below as "Low," "High," or "Unclear."

#### Rating of individual items:

#### 1.Selection bias

#### **Domain: Random sequence generation**

(<u>Support for judgement:</u> Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.)

#### Was the allocation sequence adequately generated?

Low risk High risk Unclear risk

#### Domain: Allocation concealment?

(Support for judgement: Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment)

#### Was allocation adequately concealed?

Low risk High risk Unclear risk

Comment			

#### 2a. Performance bias (of ONE primary clinical outcome)

# <u>Domain: Blinding of participants and "treating" personnel - i.e. the person(s) delivering the intervention.</u>

(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

# Was knowledge of the allocated intervention adequately prevented during the study? Low risk High risk Unclear risk Outcome NR

#### 2b. Performance bias (Medication adherence)

#### Domain: Blinding of participants and personnel

(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

# Was knowledge of the allocated intervention adequately prevented during the study? Low risk High risk Unclear risk Outcome NR

#### 2b. Performance bias (Physical activity)

#### Domain: Blinding of participants and personnel



(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

# Was knowledge of the allocated intervention adequately prevented during the study?

Low risk High risk Unclear risk Outcome NR

#### 2b. Performance bias (Diet)

#### **Domain: Blinding of participants and personnel**

(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

### Was knowledge of the allocated intervention adequately prevented during the study?

Low risk High risk Unclear risk Outcome NR

#### 2b. Performance bias (Smoking)

#### **Domain: Blinding of participants and personnel**

(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

### Was knowledge of the allocated intervention adequately prevented during the study?

Low risk High risk Unclear risk Outcome NR

#### 2c. Performance bias (Self efficacy)

#### **Domain: Blinding of participants and personnel**

(Support for judgement: Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

#### Was knowledge of the allocated intervention adequately prevented during the study?

Low risk	High risk	Unclear risk	Outcome NR	
Comme	ent			

#### 3a. Detection bias (of ONE primary clinical outcome):

#### **Domain: Blinding of outcome assessment**

(Support for judgement: Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)

#### Was knowledge of the allocated intervention adequately prevented from outcome assessors? Low risk High risk Unclear risk Outcome NR

#### 3b. Detection bias (Health behavior.):

#### Domain: Blinding of outcome assessment

(Support for judgement: Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.)



Comment	
3c. Detection bias (Self efficacy): <u>Domain: Blinding of outcome assessment</u> (Support for judgement: Describe all measures used, if any, to blind outcome a knowledge of which intervention a participant received. Provide any information reintended blinding was effective.)  Was knowledge of the allocated intervention adequately prevented from outlow risk High risk Unclear risk Outcome NR	elating to whether the
Comment	
4. Attrition bias: <u>Domain: Incomplete outcome data</u> (Support for judgement: Describe the completeness of outcome data for each rincluding attrition and exclusions from the analysis. State whether attrition and exclusions in each intervention group (compared with total randomized participa attrition/exclusions where reported, and any re-inclusions in analyses performed by the complete outcome data adequately addressed?  Low risk High risk Unclear risk	clusions were reported ants), reasons for
Comment	
5. Reporting bias: <u>Domain: Selective outcomes reporting</u> (Support for judgement: State how the possibility of selective outcome reporting review authors, and what was found.)  Are reports of the study free of suggestion of selective outcome reporting? they will measure an outcome but do not report it)  Low risk High risk Unclear risk	
Comment	
6. Other  Domain: Other sources of bias  (Support for judgement: State any important concerns about bias not addresse in the tool.  If particular questions/entries were pre-specified in the review's protocol, respons for each question/entry.)  Are reports of the study free from other bias due to problems not covered a	es should be provided
Low risk High risk Unclear risk  Comment	



## Overall risk of bias rating Low Unclear High

Narrative:			

Risk of Bias	Interpretation	Criteria
Low risk of bias	Bias, if present, is unlikely to alter the results seriously	Adequacy of random sequence generation, allocation concealment, and blinding scored as "low risk of bias" and no important concerns related to the other domains.
Unclear risk of bias	A risk of bias that raises some doubts about the results	One or two domains are scored "not clear" or not done.
High risk of bias	Bias may alter the results seriously	More than 2 domains are scored as "not clear" or not done

<sup>\*</sup> Items contained in Cochrane Risk of Bias Tool

## **QUALITY ASSESSMENT RESPONSE TABLE**

For full study citations, please refer to the report's main reference list.

Study <sup>a</sup>	1a	1b	2a	2b	2b	2b	2b	2c	3a	3b	3с	4	5	6	Overall Risk of Bias Rating
Annesi 2011 <sup>22</sup>	UR	UR	NR	NR	NR	NR	NR	UR	NR	NR	UR	LR	LR	LR	HR
Appel 2011 <sup>23</sup>	LR	UR	LR	NR	NR	NR	NR	NR	LR	NR	NR	LR	LR	LR	UR
Blackberry 2013 <sup>24</sup>	LR	LR	LR	NR	NR	NR	NR	LR	LR						
Bostrom 2016 <sup>25</sup>	LR	LR	NR	NR	HR	NR	NR	NR	NR	LR	NR	UR	LR	LRb	LR
Brodin 2008 <sup>26</sup>	LR	HR	NR	NR	HR	NR	NR	NR	NR	LR	NR	HR	LR	LR	HR
Browning 2014 <sup>27</sup>	UR	UR	LR	NR	NR	NR	NR	NR	LR	NR	NR	LR	LR	LRº	UR
Cinar 2014 <sup>28</sup>	UR	LR	LR	LR	UR	UR	UR	UR	LR	LR	LR	HR	LR	LR	UR
Damschroder 2014 <sup>29</sup>	LR	UR	HR	NR	HR	HR	NR	NR	HR	HR	NR	LR	LR	LR	HR
Frosch 2011 <sup>21</sup>	LR	LR	LR	HR	HR	HR	NR	NR	LR	HR	NR	UR	LR	LR	UR
Glasgow 2003 <sup>30</sup>	UR	UR	LR	NR	UR	UR	NR	NR	LR	UR	NR	LR	HR	HR	HR
Hawkes 2013 <sup>31</sup>	LR	LR	UR	NR	UR	UR	UR	NR	UR	UR	NR	LR	LR	LR	UR
Holland 2005 <sup>32</sup>	LR	UR	UR	NR	HR	NR	NR	NR	UR	UR	NR	UR	LR	LR	UR
Karhula 2015 <sup>33</sup>	LR	LR	LR	NR	NR	NR	NR	LR	LR	LR	LR	UR	UR	UR	UR
Kim 2015 <sup>34</sup>	HR	HR	LR	NR	NR	NR	NR	HR	LR	NR	HR	HR	LR	UR	HR
Knittle 2015 <sup>35</sup>	LR	LR	NR	NR	HR	NR	NR	HR	NR	LR	LR	LR	LR	LR	UR
Lin 2013 <sup>16</sup>	LR	LR	LR	NR	NR	LR	NR	NR	LR	LR	NR	LR	LR	LR	LR
Luley 2014 <sup>36</sup>	UR	UR	LR	NR	HR	HR	NR	NR	LR	LR	NR	LR	LR	LR	HR
Ma 2013 <sup>37</sup> (Azar 2013 <sup>38</sup> )	LR	LR	LR	NR	NR	NR	NR	NR	UR	NR	NR	LR	LR	LR	LR
McMurray 2002 <sup>39</sup>	LR	UR	UR	UR	NR	NR	NR	NR	LR	NR	NR	UR	LR	LR	UR
Nishita 2013 <sup>40</sup>	LR	LR	HR	NR	NR	NR	NR	HR	LR	NR	LR	LR	LR	LR	UR
Patja 2012 <sup>41</sup>	LR	UR	LR	NR	NR	NR	UR	UR	UR	UR	UR	HR	LR	LR	UR
Pearson 2013 <sup>19</sup> (Pearson 2012 <sup>42</sup> )	UR	UR	UR	NR	NR	UR	NR	NR	UR	UR	NR	HR	UR	LR	HR
Pinto 2015 <sup>43</sup>	UR	LR	NR	NR	UR	NR	NR	NR	NR	UR	NR	LR	LR	LR	HR
Ruggiero 2010 <sup>44</sup>	UR	UR	LR	NR	NR	NR	NR	NR	LR	NR	NR	UR	LR	LR	UR
Ruggiero 2014 <sup>20</sup>	LR	UR	LR	NR	UR	UR	NR	NR	LR	UR	NR	HR	UR	LR	HR

Study <sup>a</sup>	1a	1b	2a	2b	2b	2b	2b	2c	3a	3b	3с	4	5	6	Overall Risk of Bias Rating
Sacco 2009 <sup>45</sup>	HR	UR	LR	NR	UR	UR	NR	UR	LR	UR	UR	UR	LR	LR	UR
Safford 2015 <sup>46</sup>	LR	UR	LR	NR	NR	NR	NR	HR	LR	NR	HR	HR	LR	LR	HR
Sandroff 2014 <sup>47</sup>	LR	LR	HR	NR	HR	NR	NR	NR	HR	HR	NR	HR	LR	LR	HR
Sherwood 2010 <sup>48</sup>	UR	UR	UR	NR	NR	NR	NR	NR	UR	UR	NR	UR	UR	UR	HR
Thom 2013 #375 <sup>49</sup> (Moskowitz 2103 <sup>50</sup> )	UR	LR	LR	NR	NR	NR	NR	NR	LR	NR	NR	HR	LR	LR	UR
Turner 2012 <sup>51</sup>	LR	LR	LR	HR	NR	NR	HR	NR	LR	UR	NR	LR	UR	LR	LR
Vale 2002 <sup>52</sup>	LR	LR	HR	NR	NR	NR	NR	NR	LR	UR	NR	LR	UR	LR	UR
Vale 2003 <sup>53</sup>	LR	LR	LR	NR	HR	LR	LR	NR	LR	LR	NR	LR	LR	LR	LR
Van der Wulp 2012 <sup>54</sup>	LR	LR	NR	NR	UR	UR	NR	UR	NR	UR	UR	UR	UR	UR	UR
Varney 2014 <sup>55</sup>	LR	LR	LR	NR	HR	NR	NR	NR	LR	HR	NR	HR	UR	HR	HR
Wadden 2011 <sup>56</sup>	LR	UR	UR	NR	NR	NR	NR	NR	UR	NR	NR	LR	LR	LR	UR
Wayne 2015 <sup>57</sup>	LR	LR	LR	NR	NR	NR	NR	NR	LR	NR	NR	HR	LR	UR	UR
Whittemore 2004 <sup>58</sup>	UR	UR	LR	NR	HR	HR	NR	NR	LR	HR	NR	UR	LR	LR	HR
Willard-Grace 2015 <sup>59</sup> (Thom 2015 <sup>60</sup> )	LR	LR	LR	HR	NR	NR	NR	NR	LR	HR	NR	UR	LR	LR	UR
Wolever 2010 <sup>61</sup>	UR	UR	LR	UR	UR	NR	NR	NR	LR	LR	NR	LR	LR	LR	UR
Young 2014 <sup>62</sup>	UR	UR	NR	NR	UR	NR	NR	UR	NR	UR	UR	LR	HR	LR	UR

Abbreviations: UR=Unclear risk, LR=Low risk, HR=High risk, NR=Not reported

<sup>a</sup> The companion paper (noted in parentheses) is not rated separately in this table.

<sup>b</sup> Recall bias

<sup>&</sup>lt;sup>c</sup> Contamination

## **APPENDIX D. PEER REVIEW COMMENTS**

Question Text	Reviewer Number	Comment	Authors' Response
Are the	1	No - First, thanks so much for taking on this	We thank the reviewer for the careful review of the report,
objectives,		challenging and extremely complicated review. It's	including the critique of current definitions of health
scope, and		clear from the report that a tremendous amount of	coaching and how the decision to use self-identified health
methods for		effort went into conducting the review, completing the	coaching interventions may have impacted our results. Any
this review		huge number of analyses, synthesizing the findings	method for identifying literature for complex behavioral
clearly		and writing the report!	intervention/innovation has strengths and limitations. This is
described?			even more pronounced when the complex behavioral
		However, after reading the report, I must say that I	intervention has not been well defined and there is no
		have serious concerns about the meaningfulness of	consensus on what constitutes key elements of the
		the findings of the report due to the approaches, and	approach. Health coaching in not immune to these
		subsequently the methods, used to define health	complexities.
		coaching, identify the sample of health coaching studies, and subsequently evaluate the impact of	As illustrated in Wolever's 2011 Archives of Internal
		these "health coaching" interventions.	Medicine commentary, there is currently no agreement on
		These health coaching interventions.	what comprises health coaching. To date, there has also
		As a participant in the planning for this ESP project, I	been no research to establish the active ingredients of
		participated in the decision-making about the	health coaching intervention. Thus, in close consultation
		definitions of health coaching and the choice of	with our key stakeholders and our technical expert panel,
		inclusion and exclusion criteria, so I must take some	we weighed our options for identifying this literature. We
		responsibility for the subsequent impact of those	jointly decided upon use of self-identified interventions. This
		decisions. However, after seeing how the selection	approach is supported in the literature; it has been used in
		criteria impacted the sample, I am afraid that the	at least two other recent systematic reviews of health
		criteria used to identify health coaching interventions	coaching: (1) Olsen JM, Nesbitt BJ. Health coaching to
		for the ESP raise serious doubts and limitations	improve healthy lifestyle behaviors: an integrative review.
		about the meaningfulness of the findings.	Am J Health Promot. 2010;25(1):e1-e12, and (2) Kivela K,
			Elo S, Kyngas H, Kaariainen M. The effects of health
		Despite the efforts of the ESP team and key	coaching on adult patients with chronic diseases: a
		stakeholders to choose meaningful inclusion and	systematic review. Patient Educ Couns. 2014;97(2):147-
		exclusion criteria for the ESP review, I believe that	157. Also, Wolever's seminal systematic review focused on
		the decision to select studies based on authors' "self-	how health coaching has been defined in the literature:
		identification" of an intervention as a health coaching	Wolever RQ, Simmons LA, Sforzo GA, et al. A systematic
		intervention seriously limits the value of the	review of the literature on health and wellness coaching:
		subsequent analyses and meaningfulness of the	defining a key behavioral intervention in healthcare. Glob
		findings. Conceptualizations of health coaching vary	Adv Health Med. 2013;2(4):38-57.
		across investigators, even among those who label	
		their intervention as health coaching. To my point, if I	



Question Text	Reviewer Number	Comment	Authors' Response
		counted correctly, only 14 of the 41 studies in the	We recognize that any approach to identifying this literature
		sample were found to include all 3 of the prioritized	would introduce heterogeneity. Thus, we sought to unpack
		components of health coaching identified by	this complexity by applying a health coaching concordance
		stakeholders; only 68% had the highest priority	standard across the identified literature. This concordance
		patient-centeredness element; while 5 studies had	score was co-developed with stakeholders, technical expert
		none of the 3! So, almost 2/3 of the selected studies	panel members, and local experts in health coaching.
		did not include all 3 high priority health coaching	Although we agree that it was surprising to find a high
		elements. Thus, there is clearly a lack of consistency	number of studies that did not include all three elements,
		among the investigators of the selected trials	our intent was not to characterize interventions as meeting
		regarding the conceptualization of health coaching.	health coaching criteria if these three elements were
		And, because the inclusion of studies was largely	present. Rather, we were interested in examining the
		based on self-identification of health coaching, it is	relationship between concordance with key elements and
		also highly likely that many interventions that might	select outcomes.
		have been included in the sample, based on the	
		health coaching definition used in the ESP, were not	We also agree that these key elements are not unique to
		included because they did not use coaching as a	health coaching. Many behavior change approaches share
		descriptor in their title or abstract or key words.	common elements and, as the reviewer states, there is
		To site it at 4 example of the impost of the decision to	significant overlap in approaches. It is precisely for that
		To cite just 1 example of the impact of the decision to	reason that we tasked our collaborators and external
		use self-identification as a key determinant of	experts with prioritizing key elements of health coaching.
		inclusion, the Pinto et al study that was included in the sample of 41 health coaching studies utilized a	The reviewer's assessment that these key elements were not applied to a high degree across studies and that there is
		physical activity counseling intervention that is almost	overlap in approaches are excellent points that we now
		identical in content and approach to interventions that	1
		were utilized by the same investigators in multiple	conclusions. Health coaching is an emerging field with
		previously published physical activity intervention	shifting definitions across time. Our approach offers a
		trials. I was a member of the investigative team for	snapshot of the literature at the current time. The
		several of these studies, so I am quite sure the	heterogeneity of the identified studies underscores the
		intervention approach was the same, except for the	importance of better efforts to distinguish health coaching
		use of peers to deliver the counseling intervention in	from other common behavioral interventions. We have
		the selected study (I'm happy to share the citations of	expanded our Discussion section to include a broader
		other trials with you). Yet, because we did not	discussion of the variability of the included study.
		previously use the term coaching in the title, abstract	
		or key words of the previous publications, they did	
		not meet inclusion criteria and were not included this	
		ESP review. I believe there are probably many other	
		examples of investigators who inconsistently labeled	
		their intervention as health coaching. I am also quite	
	1	sure that there are many studies that applied an	

Question Text	Reviewer Number	Comment	Authors' Response
		intervention that would meet the definition of health coaching that were not included for this ESP because the intervention was labeled differently (e.g., as behavioral counseling, self-management support, motivational interviewing, health education).	
		Moreover, I would argue that health coaching, as conceptualized in this ESP, is as an interactive "process" that is a core component of a wide range of health behavior change interventions, rather than a specific intervention type. And, the 3 prioritized elements of health coaching specified in the ESP, are key elements of many theoretically derived health behavior change interventions, including those based on self-determination theory, the transtheoretical model, the health belief model, the PRECEDE-PROCEED model, social cognitive theory, motivational interviewing and the 5As (Assess, Advise, Agree, Assist, Arrange). See the Whitlock et al publication for a model that was developed to assist the USPSTF evaluate the impact of health behavior counseling interventions in primary care. The authors also promote the use of the 5As as "a unifying construct to describe behavioral counseling interventions across behaviors". The 5As approach, as described by Whitlock, clearly includes the 3 high	
		priority elements of health coaching specified in the ESP report, along with other key elements that are linked to health behavior change theoretical models. [Citation: Whitlock P, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence- based approach, Am J Prev Med 2002;22:267–84.] –	
		Because there is extensive overlap between self- identified health coaching interventions, self-identified health behavior counseling interventions and self- identified self-management support interventions, use of self-identification as a key inclusion criteria	

Question Text	Reviewer Number	Comment	Authors' Response
		elevates use of a descriptive label as THE differentiating feature. And because this label is inconsistently and idiosyncratically applied, it reduces the meaningfulness of the findings of the review.	
		I have offered some other specific examples of the limitations of using self-identified health coaching as a selection criteria in the "additional comments" section below.	
		Unfortunately, at this point in the ESP process, there is not much that can be done to address the inclusion/exclusion issue. However, as authors of the report, it would be helpful to more clearly discuss the limitations of the report, specifying how the limitations raises increased uncertainty about the meaningfulness of the findings. As noted in my response to the question about bias below, I feel that the Clinical Implications and Conclusions sections overstate the meaningfulness of the findings and could more directly reflect the significant methodological limitations. —	
		See also the very recent article by Larsen et al in the February 2017 issue of the J of Behavioral Medicine - "Behavior change interventions: the potential of ontologies for advancing science and practice". The authors offer a very cogent argument for developing and applying common language for characterizing key aspects of behavioral interventions to aid efforts to tease apart elements responsible for impacting behavioral outcomes within specific populations and contexts. Using their "entellogy", elements of health	
		contexts. Using their "ontology", elements of health coaching would fall into the "Intervention Delivery" class - "Includes mode of delivery including face-to-face, telephone, SMS text, mobile app, website, mass media etc. It also involves style of delivery such as engagement features of an app, or communication style of a counsellor. It also includes duration,	

Question Text	Reviewer Number	Comment	Authors' Response
		amount, and fidelity to designed content". Larsen et al also define Intervention Content - "What is delivered by the intervention in terms of behavior change techniques (BCTs) and intervention functions. BCTs are potentially active ingredients that may be specified in terms of an appropriate taxonomy which may be mapped on to Michie et al's BCT Taxonomy v1 taxonomy". We would have to delve deeper into this ontology to determine where health coaching might fall - my guess is that it would include elements of both "delivery (particularly counselor "sytle") and "content". As Larsen point out, use of a more precise common language will aid evaluation of intervention element impact as well as conditions for effects and mechanisms. As Larsen and colleagues note, "The goal of this ontology is to provide a means of answering the question, 'What works to change what behaviors, for whom, in what situations, how and why?'. This approach may help guide future research on the impacts of key intervention elements, including those identified by the ESP team and stakeholders as prioritized elements of health coaching.	
	2		
	3		
	4	1.55	
	5		
	7	Yes	



Is there any indication of bias in our synthesis of the evidence?

1 Yes - See response to the question on objectives, scope and methods, as well as additional comments.

The authors are aware of limitations due to the lack of consensus on a definition of health coaching and the selection of studies based self-identification as health coaching interventions. These are clearly mentioned as limitations on page 79. However, my overall impression upon reading the report is that the authors do not fully appreciate nor specify the potential impacts of the limitations on the results.

Though other important limitations are noted (e.g, only 15% of selected studies were judged to have low risk of bias; high levels of heterogeneity; lack of any consistent relationships between study characteristics and outcomes; inability to conduct multivariate analyses of study characteristics), these limitations are not adequately reflected in the language used to summarize findings, particularly in the Clinical Implications and Conclusions section.

Given the serious limitations, I respectfully disagree with the conclusions (on page 81) that the "overall results suggest self-identified health coaching have the potential to produce small positive statistically significant effects..." and "compared with usual care, health coaching interventions may be as effective as other behavior change techniques". Though the language, "has the potential to" and "may be as effective as...." reflects uncertainty regarding the strength of evidence supporting the findings, I feel the limitations are such that it is important to be clearer about the limitations and the uncertainty of the findings, especially in the clinical significance and conclusion sections. As noted, there were significant problems reliably characterizing and identifying health coaching interventions an differentiating these from other interventions that focus on health behavior change.

Thank you for these comments. We have expanded our Conclusion section to place greater emphasis on the need for several foundational steps to occur prior to additional research on the effectiveness of health coaching. These proposed steps include the development of consensus definitions of health coaching and the credentials required to become a certified health coach, greater attention to behavior change taxonomies when developing and describing interventions, and more rigorous publication standards requiring more complete description of study design, randomization, and reporting.

We have made revisions throughout our Discussion section. We have retained this language in the Conclusion section: "However, the relatively large number of studies at high or unclear ROB and the moderate to high heterogeneity in pooled estimates limit certainty about the interpretation of our findings and the conclusions that may be drawn."

2 No



Question Reviewer Text Number	Comment	Authors' Response
3	Yes - It is not biased in the sense of being inconsistent or favoring a specific outcome, but is biased in the sense that evaluation criteria for biomedical studies was applied without adequate attention to the fact that these are behavioral trials that warrant different criteria in assessing quality. Specifically, the rating of unclear bias for behavioral trials that did not blind participants to randomized intervention is not appropriate for behavioral trials of this nature. Hence, the quality of the available research (while still low to moderate and in need of stronger designs) is portrayed as lower than it is. Similarly, the use of wait-lists and usual care (seen as less rigorous for biomedical studies) is more appropriate than most other designs in many of the health coaching studies yet is consistently described in the report as providing "weaker" research. (For example see the work of K. Freedland, editor of Health Psychology. e.g., Freedland KE. Demanding attention: reconsidering the role of attention control groups in behavioral intervention research. Psychosom Med. 2013;75(2):100-102; Freedland KE, Mohr DC, Davidson KW, Schwartz JE. Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. Psychosom Med. 2011;73(4):323-335.) Most of the health coaching studies are pragmatic effectiveness trials, not efficacy trials, and have the goal of evaluating potential improvement in clinically important outcomes rather than the goal of "analysis in isolation" used in most biomedical studies. I am so sorry that I was not aware of the plans to apply Cochrane criteria to rate quality or I would have raised this issue when my input was first invited.  An additional issue related to the lack of understanding of behavioral trials is that weight/BMI is consistently categorized as patient "behaviors" in KQ1 throughout the report. Weight and BMI, though	We thank the reviewer for this important point. We now reference the detailed guidance for the Cochrane Risk of Bias Evaluation Tool in Appendix C (Higgins J, Altman DG. Chapter 8: Assessing risk of bias in included studies. In Cochrane Handbook for Systematic Reviews of Interventions Version 5.0, 2008. Available at: <a href="http://handbook.cochrane.org/chapter-8/8">http://handbook.cochrane.org/chapter-8/8</a> assessing risk of bias in included studies.htm.)  These criteria allow for unblinding of participants and an assessment of low risk of bias. Prior to beginning the risk of bias evaluation process, our study team was rigorously trained in how to properly apply these criteria to behavioral interventions. Also we added additional information to our limitations section describing the fact that many studies did not fully report information on their study design for reviewers to properly assess bias. This resulted in many components of bias being deemed "unclear" and overall ratings resulting as "high risk."  The reviewer also introduces an interesting idea about the language we use to describe usual care comparators. We have modified our language to map to this excellent point.  We have now used the term "weight management" to describe studies assessing the outcome of weight loss as measured by changes in weight (lb/kg) or BMI.

Question Text	Reviewer Number	Comment	Authors' Response
	4	highly related to behavior, are clinical outcomes - not patient behaviors. (A person can not "do" weight; they eat or don't exercise and weight may be the result, just like dysregulated blood sugar.) That this categorization is inaccurate is also evident when the authors note diagnostic categories of patients, including obesity with the categories of type 2 diabetes, heart disease, etc. (e.g., see p. 12 line 26; and throughout the results - e.g., p. 64 line 23); obesity is a clinical condition not a behavior.  Yes - In my assessment of current literature, including this study, there is a core misunderstanding or lack of understanding of what health coaching is,	Thank you for these comments. Patient-centeredness was one of our <i>a priori</i> key elements of health coaching in the concordance score. In fact, our advisors rated it as the most
		and why it is different from case or disease management, education, or directed behavioral instruction. The bias that is pervasive is that of a reductionistic, linear cause and effect model of disease and healing. The greatest potential gains from the introduction of Health Coaching into the current medical system is it bringing an approach that shifts the entire orientation toward the patient/client within our system of health care. Putting Health coaching into a directed intervention like a drug, without understanding its core nature, is doing a disservice to the potential it can bring.	important element. Thus, a study was given one point for demonstrated use of patient-determined goal or use of self-discovery process and 2 points for patient-centeredness, as this was rated as the main driver of coaching effects by our stakeholders.
	5	No	
	7	No	

Question Text	Reviewer Number	Comment	Authors' Response
Are there any	1	Yes - See other comments.	
<u>published</u> or	2	No	
unpublished studies that we may have overlooked?	3	Yes - In general the search was very thorough, but it was unclear to me why some trials were left out. For example, the Duke study by Edelman et al (2006) was clearly a health coaching trial. Perhaps it was left out because there were multiple elements to the intervention in addition to coaching. However, that was also the case for included trials such as Wennberg (2010), Appel (2011) or Annesi (2011), so selection was unclear to me. It would be helpful to have a clarifying statement regarding how inclusion decisions were made when the intervention had both coaching and other elements (and had a sample with chronic disease).	Our initial literature search captured this Edelman et al study (2006). However, our inclusion criteria states that eligible studies needed to be designed to recruit individuals with one or more chronic medical condition. This study sought to recruit patient with elevated CVD risk, not a pre-existing chronic medical condition. In an assessment of the recruited population, it is possible that up to 40% of the sample may only have had a risk factor and no preexisting chronic medical condition. Further, we consulted with the primary author of this study, who is also an author of this report, and he agrees that the eligibility criteria for this systematic review doesn't map to the population he sought to recruit for his study. We have clarified our eligibility criteria in Table 1 to better reflect populations deemed eligible for this systematic review.
	4	Yes - I believe the original decision to include only RCT's eliminates significant data that can be gained from other published studies,, See Levin, Jeffrey S., et al. "Quantitative methods in research on complementary and alternative medicine: a methodological manifesto." Medical care 35.11 (1997): 1079-1094.	We agree that limiting to RCTs eliminates data that may be contained in other studies with non-RCTs designs. It would have been infeasible to include other designs without limiting the review in other ways, such as limiting populations or outcomes of interest. As our stakeholders were interested in the effectiveness of health coaching across a wide swath of populations and outcomes, and there were ample literature, we limited the evidence base to the most rigorous study design. We, however, now state in our limitations section that restricting to RCT is a limitation.
	5	Yes - I only saw two studies on diabetes prevention program. Health coaching is part of the intervention. Dr. Robert Ackermann has published in this area and I didn't see any of his articles.	Our systematic review's eligibility criteria specify that populations must have a chronic medical condition. Thus, studies of disease prevention would have been excluded. We have clarified our eligibility criteria in Table 1 to better reflect populations deemed eligible for this systematic review.
	7	No	

Additional suggestions or comments can be provided below. If applicable, please indicate the page and line numbers from the draft report.

page 2, line 24 - I think you meant to say "decreases" in HbA1c. My comments regarding the Abstract conclusions are noted in my responses to reviewer question on bias above.

page 3, line 51 - I have some trouble with the statement, "While health coaching shares common elements with other intervention approaches such as patient education and disease management, health coaching differs in its emphasis on both the overall approach and the process." The first part of the statement is accurate, but the latter part ("health coaching differs in its emphasis....") is an overgeneralization. Though "patient education" may be delivered by a directive or didactic manner by some (e.g., those who have not received training in contemporary health education approaches), health education is, by definition, a process that overlaps quite considerably with the definition of health coaching applied in this ESP project. NCP's Veterans Health Education and Information (VHEI)program defines health education as follows: "Health education is a process that includes any combination of education, information, and other strategies to help Veterans optimize their health and quality of life. Health education programs and services assist Veterans to adopt healthy behaviors, partner with their health care teams, make informed decisions about their health, manage their acute and chronic conditions, and use problem-solving and coping skills." This definition aligns with published health education theory and with models of health education research, training and practice that feature collaborative, patient-centered approaches. To cite just one example, in 1980, in their book, Health Education Planning: A Diagnostic Approach, Green, Kreuter and others described the PRECEDE Model. which featured assessment of individual predisposing, enabling and reinforcing factors when developing and delivering health education interventions. The PRECEDE approach requires

The direction of effects is reflected in the point estimates.

There are numerous definitions of health education that range from a narrow intervention approach to a field of social science. However, health coaching is conceptualized as an intervention approach which can be considered one tool, or approach, used in the field of health education. Our intent in the introduction was not to draw a contrast between the field of health education and the intervention approach of health coaching. We have modified the introduction to better emphasize the differences in approaches between traditional patient education, not the field of health education, and emerging models of collaborative intervention, like health coaching.

The reviewer asks how we defined "patient education only" and "disease management only." Again, we allowed the study authors to categorize their own intervention approaches.

The moderators we explored were suggested by, and developed with, our stakeholders. Training, supervision and in-study monitoring of fidelity were not selected as key variables to explore. We agree with the reviewer that these are important component of implementing high quality behavioral interventions. It is important to note that these elements are not routinely reported in outcomes papers of behavioral interventions, especially in-study monitoring of treatment fidelity. Even when fidelity is reported, the description usually contains the process of assessing treatment fidelity and not the degree to which the implementation of the intervention maps to the intended content and approach of the intervention. Thus, conducting such analyses are likely infeasible. We did routinely collect how interventionists were trained, if these descriptions were present in the studies. We have added information on the variability in coach training in the description of the included studies. Also our future research table lists training as a key area for future research.

actively engaging patients, exploring their values, needs and preferences, and tailoring interventions to these elements. Health education interventions have also been informed by other theories and models (e.g., Health Belief Model, Social Cognitive Theory, TTM, Self-Determination Theory) that emphasize an interactive patient-centered process. See my next comment as well.

page 3, line 55 - 58. The statement, "traditional health education interventions are more likely to be expert directed, task oriented and focused on disease-specific content, whearas health coaching is collaborative, client-centered and more likely to be focused on the whole person", is misleading and and does not accurately characterize the current state of health education programs, most of which embrace collaborative patient-centered principles. Please see my previous comment regarding health education as a collaborative patient-centered process. Another example of the collaborative nature of health education programming is Holman and Lorig's characterizations of self-management and selfmanagement support. (See: "Patients as Partners in Managing Chronic Disease, BMJ, 2000). Indeed, contemporary health education programs actually feature "health coaching" components (as defined in the ESP) and refer to them as critical and essential elements. (Note: the VHA VHEI Program has published a "Veteran-Centered Health Education Workbook" that features strategies for enhancing the patient-centeredness of VHEI programming.(It is available upon request).

Though I understand the ESP investigators' need to focus in on health coaching interventions and could be differentiated from large volume of health education and self-management support interventions that have been investigated in clinical trials, it is not accurate to imply that all patient education interventions are any less collaborative than health coaching interventions. The presence of

We have added to our Discussion section that there is overlap in the concordance elements and elements of other health behavior change approaches.

It is an interesting idea to compare the proportion of low risk of bias studies in this report to systematic reviews of other interventions designed to impact chronic illness outcomes. There is a high degree of variability in how study quality is assessed (tool used, domains assessed) and reported (overall score qualitative score, numerical score, by bias item vs overall score) across systematic reviews. Also these risk of bias assessment approaches and applications vary based on the type of interventions being reviewed. Further, while PRISMA calls for an assessment of risk of bias, many systematic reviews do not conduct such assessments. Thus, comparing our assessment of overall risk of bias to other studies is likely infeasible and unadvisable based on the reasons stated here.

In the Clinical Implications section we state that "For HbA1c, there is consensus that improvements of 0.3%, the summary effect found in this study, are clinically relevant changes. .." While we have added that other nonpharmacologic interventions have produced equal or greater effects, it should be noted that the Chodosh et al (Ann Intern Med 2005) study included a definition of disease self-management that study authors stated was very broad and likely included studies that other may not have included in a review of disease self-management, summary effects demonstrated important heterogeneity, which means that this effect size must be interpreted with caution, and the review is over 10 years old making comparisons to this literature review imprudent.

Regarding the Pinto et al study, we have stated throughout the report the strengths and limitations of our approach to identifying the literature on health coaching.

We are in agreement that several of the interventions included in the weight management sections of the report do not meet criteria set forth for comprehensive lifestyle



health coaching consistent elements in patient education programs may help explain the ESP's finding of a limited effect of health coaching vs "active comparators", as many of the "active" health education comparators also have patient-centered, collaborative "whole person" components. On the other hand, exclusion of patient education interventions from the sample of health coaching interventions may have limited the likelihood of finding positive effects for health coaching on the chosen outcomes. For example, self-management support interventions for diabetes, which I have argued almost always include process elements that overlap substantially with the elements of health coaching, have demonstrated a positive effect on HbA1c in previous meta analyses (See Chodosh, AnnIM 2005). The exclusion of these "healthcoaching like" patient education interventions also limited the analysis of processes that contribute to positive intervention effects.

page 5, Table 1. How was "patient education only" and "disease management only" defined? How confident were the reviewers that those identified as patient education and disease management only did not meet the criteria for inclusion as a health coaching intervention? It seems like many selfmanagement support interventions excluded. I noted the list of included studies does not include most Lorig et al self-management support program (CDSMP) interventions and Heisler's peer coaching for diabetes self-management studies, both of which had robust "health coaching" elements.

page 8 - The analyses did not include training, supervision and in-study monitoring of fidelity as a potential source of variability. I realize that the number of possible determinants of variability had to be limited for this ESP. A more targeted analysis that includes these potential fidelity-related sources of heterogeneity should be considered in subsequent

interventions. It was not the charge of this report to assess CLI and, thus, beyond the scope of these analyses.

We have stated that many of the outcomes used in our analyses were not the main outcomes of each of the studies. Pooling secondary outcomes is not an uncommon practice in systematic review science.

Thank you for your ideas on future research. We have expanded our list of future research, including a call for some formative research on the key elements of health coaching that distinguish it from other behavioral approaches.

We have modified our concluding statement about the effectiveness of health coaching in relationship to other behavioral approaches and have reiterated that there were multiple adjunctive intervention supports across the included trials in response to the reviewer's keen comments.



evidence synthesis reviews of health coaching or health behavior counseling interventions.

page 8 - 9 - rating of prioritized elements of health coaching. This is a strength of the analyses. Again, I will point out the 3 elements that were chosen are common to most "modern" (and particularly 21st century) health education and self-management support interventions. Even when the SMS is offered in the setting of a chronic condition that focuses on a specific set of self-management behaviors (e.g., the American Association of Diabetes Educators "7"), self-management support interventions feature patient-centered approaches, offer a large menu of possible diabetes SM goals, and engage the patient in an active discovery process.(Note - see Fisher, Ecological Approaches to Self-Management, AJPH, 2005 and the Resources and Supports for Self-Management (RSSM) measure that was developed to capture the elements of effective SMS https://www.ncbi.nlm.nih.gov/pubmed/18669813)

page 12, line 25 - "Most studies recruited populations with type 2 diabetes (n = 18) I think you meant to state, "the most common population recruited was type 2 diabetes".

page 12, line 44. "only 15% trials (6 studies) had a grade of low risk of bias......34% of trials (n = 14) had a high risk of bias". It would be useful to comment either here or subsequently on the very small percentage of studies that were judged as low risk of bias. How does this compare with other similar meta analyses of interventions designed to impact chronic illness outcomes?

page 22 - Studies reporting change in HbA1c. Note that the mean difference of .3% found for self-identified health coaching vs an inactive comparator is well below the .81% difference found in the meta-



analysis of self-management support interventions among older adults with diabetes conducted by Chodosh et al, AnnIM, 2005).

page 26 - Effects on Physical Activity. See my comment in response to the methods question regarding Pinto et al PA studies.

page 29 - Effects on Weight, BMI. As previously noted, the selection criteria focused on selfidentification of health coaching and this has led to inconsistent inclusion and exclusion of weight loss intervention trials. For example, 2 of the 3 NIHsupported POWER trials are included in the ESP review (Wadden and Appel are included, Bennett et al., ArchIM, 2012 is not), even though the interventions for all 3 trials based their obesity interventions on the Diabetes Prevention Program trial, a comprehensive lifestyle intervention, and was adapted to be compatible for delivery within primary care settings. (Note: Systematic reviews and metaanalyses of behavioral weight loss interventions, conducted by AHRQ, AHA/ACC/TOS, as well as the VA/DoD Clinical Practice Guideline, identified core intervention elements associated with clinically significant weight loss. These reviews also concluded that interventions that don't meet the criteria for CLI are less likely to produce clinically significant weight loss. Based on these systematic reviews of evidence , the AHA/ACC/TOS and VA/DoD guidelnes recommend the provision of comprehensive lifestyle interventions (CLI) as a core element of overweight and obesity management. The VA/DoD CPG specifies that CLIs must include 3 key components (dietary, physical activity and behavior change components), and at least 12 clinical sessions in 12 months.) Several of the interventions included in the ESP analysis do not meet criteria for a CLI. Moreover, many included a weight loss outcome measure, but did not focus on weight loss as a primary objective. (This was mentioned but not



emphasized by the authors). Moreover, as discussed by the authors, the non-health coaching elements of the interventions that were included in the ESP's BMI change and weight loss analyses are quite heterogeneous. As a result, the meaning of the findings of the ESP analyses on BMI and weight are uncertain and potentially confusing to readers. The small effects found for reducing BMI across highly heterogeneous studies, populations, and contexts does not, in my opinion, provide support for health coaching as an independent contributor to weight loss and once certainly shouldn't imply from this finding that health coaching may be as effective as a CLI (yet that is what the conclusion implies).

Note also, that, in the ASPIRE VHA-based trial, cited on page 32, all 3 interventions met the criteria for a CLI and all produced significant weight loss. Moreover, at follow-up, there was no significant difference in weight loss across arms, despite the increased support provided to interventionists who delivered the enhanced health coaching arm.

From the perspective of NCP, it is critically important that VHA continues to focus on disseminating and implementing CLIs for weight management that meet the criteria recommended by current VA/DoD guidelines, which in turn are based on rigorous synthesis of the best available evidence. On the other hand, gaps in our understanding remain about how to best help patients to engage and participate in weight management interventions as well maintenance activities when they are successful. Focusing on the 3 priority elements of health coaching, as a COMPONENT of an evidence-based weight management intervention may be helpful in that regard. That might be a very fruitful area for future research - which might be one recommendation stemming from this report.

However, the final version of this report should at



Question Text	Reviewer Number	Comment	Authors' Response
		least mention the current CPG recommendations for weight management, including the recommendation for offering CLI. (Note also 2 publications from Wadden, one a systematic review of behavioral treatment of obesity for patients seen in primary care, and a quite recent review article from NEJM. Both reinforce the importance of offering CLI, while also considering ways to make weight management interventions more accessible and impactful, particularly in primary care settings. (Wadden et al. Behavioral treatment of obesity in patients encountered in primary care settings: a systematic review. JAMA. 2014 Nov 5;312(17):1779-91. doi: 10.1001/jama.2014.14173; Heymsfield SB, Wadden TA.; Mechanisms, Pathophysiology, and Management of Obesity.  N Engl J Med. 2017 Jan 19;376(3):254-266. doi: 10.1056/NEJMra1514009.))	
	2	The most significant issue in assessing the effectiveness of health coaching is that health coaching is an emerging profession, and is therefore not well or consistently defined. While this is stated in the review, it is not given the emphasis it deserves. While the review states that one of the characteristics assessed was the training of the 'self identified coaches' (page 6), this is not explored in the article. There is one statement that in all of the studies included there is only ONE trial that used a certified health coach (pg 12)- that is a SIGNIFICANT finding.  A very critical issue is that when people self identify as a health coach, at a time when the profession has not been defined, there is huge disparity in the intervention and therefore "mixed results." As I read the descriptions, it seems to me that the common denominator is more likely to be motivational interviewing, and in some studies, even case management, but not what the profession is now defining as health coaching.	We agree with this reviewer and have further highlighted that only one study describes use of "certified health coaches" and the impact that may have on heterogeneity of treatment effects.

Question Reviewer Text Number	Comment	Authors' Response
	This in no way diminishes the results of the systematic review, but I do feel this factor is not appropriately emphasized. To use an illustration from my profession, it is parallel to trying to draw conclusions about labor and delivery outcomes when looking at pregnancy outcomes of women managed by ObGyns, nurse midwives, and lay midwives combined - all trained in different approaches with vastly different levels of training, and yet all included in the analysis.	
	I applaud the authors for this enormous project that entailed countless hours of careful attention. Thank you for this work! I understand why the authors focused on interventions self-described as health coaching given the nascent state of clear definitions for the approach, and yet I am disappointed that we are left with a confounded presentation of the findings of health coaching interventions. Many of the included trials do not fit with the emerging definitions of health coaching [e.g., as put forth in the literature by Wolever, Simmons et al, 2013 (and adopted by the National Health Service in the UK, or that put forth by Olsen & Nesbitt, 2010 or by the International Consortium for Health & Wellness Coaching in partnership with the National Board of Medical Examiners]. The fact that the interventions studied include many that are not health coaching is obvious in the low percentages of trials that met any of the three critical elements defined by stakeholders. That said, it is very useful to have such a comprehensive and systematic work that does show the state of the literature, with all of its problems. My biggest concerns regard the treatment of this literature as if it were biomedical in nature rather than behavioral (as already noted above). Aside from that, I offer specific comments to consider, some of them just typos to	Thank you for these observations and your careful reading of the report. We have corrected the typos on the text and provided further clarification in the places the reviewer identified. Moreover, we have clarified our use of risk of bias elements above as they apply to behavioral interventions.  We have clarified that the duration described in the study characteristics pertains to the active intervention phase and not the outcome assessment window.  Unless otherwise noted, effect estimates are means at follow-up. We have clarified this in our methods section. For weight outcomes and A1c we preserved the natural units and used mean differences (MD) and for other outcomes that were more variable, we used standardized mean differences (SMD). This is noted on each forest plot and in the text of each results section per outcome.  We considered including patient activation as an outcome of interest in this study as it is an emerging outcome in health coaching. As it is an emerging outcome of health coaching, our stakeholders thought that it would not be reported consistently, especially in the early literature, prior to the availability of a measure of patient activation. Thus, per the guidance of our technical experts, we collected and analyzed self-efficacy. We have added this idea as a future



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		p. 1 line 57, remove "use" in "use used"	The p-values in the forest plots pertain to the test for heterogeneity statistic, I <sup>2</sup> , and not the summary effect estimates.
		p. 2 line 24, "increases" should read "decreases in HbA1c"	In reference to the use of the quality rating tool used in this study, review investigators were taught how to apply these
		p. 3 lines 14-15 unclear: does this mean 828 hrs per yr to treat all patients that had any of the top 10 chronic diseases?	criteria to behavioral studies, including when blinding of participants was not feasible.
		p. 3 line 42: coaches do not provide advice, including motivational advice. Better to say "is to use motivational processes,"	
		p. 3 line 51 "may not be trained therapists" - in fact, the vast majority are not, so better to say "but only the minority are trained"	
		p. 4 lines 11-12: the report was commissioned for these reasons, and I know why it understandably shifted a bit. The reader won't know this however, so an additional sentence somewhere might make it more clear why quality of life and pt satisfaction were not evaluated	
		p. 4 line 37 - as noted above, weight is not a behavior	
		p. 4 line 50 - there are several places where "certified" health coaches are mentioned. (Also seen on p. 12 line 12, p. 35 line 39, p. 69 line 5.) The naive reader (and perhaps the authors) might assume that "certified" in this context means something in terms of skill level, when it does not. In fact, at this point in time, there is no single certification that implies	
		additional skill behind its brand identity. You can literally go online, pay a fee and become certified without the demonstration of a single skill! The International Consortium of Health and Wellness Coaching is working to change this, but thus far, it is	

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		misleading to note "certified" as a way to distinguish the coaches in one study versus another (even if those authors did). I strongly recommend removing that distinction.	
		p. 6 line 14 - weight is not a patient behavior but a clinical outcome	
		p. 7 line 13 - it is inappropriate to assume that blinding participants in an active behavioral trial is an indicator of quality research. Please see discussion and refs above.	
		p. 7 line 55 - only six had more than one arm?? (UC vs coaching is two arms) Do you mean more than one active arm/intervention beyond usual care?	
		p. 8 line 25 - were funnel plots explored?	
		p. 8 line 54 - The technical expert from Vanderbilt is from the Vanderbilt University Medical Center (there is no school of PMR, but only a Department of PMR, and of Psychiatry)	
		p. 9 lines 26-27 - Did you characterize an intervention as using pt-determined goals if the participants had any input at all? Many trials have both expert/professional input as well as participant input. For example, one might get an exercise prescription (expert driven goal) but fine-tune it for their readiness. Or get the goal from the expert but have exercised some pt-determination in signing up for a study on a given behavior (e.g., aerobic exercise) in the first place.	
		p. 12 lines 43-44 - An inclusion requirement was that there was at least 6 month outcomes data, so how could only 80% of the trials last months or longer?	

Question Text	Reviewer Number	Comment	Authors' Response
		p. 12, line 56 - weight is not a behavior	
		p. 16 line 25 - Luley study comparator column is unfinished: "then control group left??"	
		p. 16, line 49 - what was the intervention duration? max of 3 X per week for how long?	
		p. 17 line 26 - needs bullet in third column	
		p. 21 line 22 - replace "medical assistant in psychology coach" with "psychotherapist" or with "masters level psychologist" - there were no medical assistants in this trial	
		p. 21 line 48 - Somewhere, (and most likely in the discussion, but it was apparent to me here) it would be useful to note that one of the challenges with health coaching trials is that since goals are self-determined, participants work on different things and inclusion criteria is not targeted to a single variable. It is easier to get significance for change in A1c, for example, when you only include those with elevated A1c to start with. But by glancing over the starting A1c values of the various trials, it is obvious that elevated A1c was not an inclusion criteria for many studies. This is similar for other conditions; when you don't start with elevated weight with all participants, harder to see a change in weight, etc. Hence, trials designs need to consider this in the future.	
		p. 24 Figure 2 - It is not clear what the mean (SD) values represent. It appears that they are sometimes the post-tx mean (without consideration for baseline) and sometimes the mean change for a given group. Is there a way to clarify this, or perhaps at least spell out that these differences are neutralized in the meta-analyses? This is similar for the other Figures - e.g.,	

Question Text	Reviewer Number	Comment	Authors' Response
		p. 24 line 58 - comma needed after cardiovascular disease	
		p. 32 line 31 - replace "students" with "participants"	
		p. 34 Figure 6 - spacing and size could be better	
		p. 35 Figure 7 - same	
		p. 35 line 38 - remove "study" after ROB	
		p. 36 line 47 - drop the "ed" on addressed	
		p. 37 line 35 - I wonder why you left out trials that measured pt activation as this concept is highly related to self-efficacy? In fact, it is defined as believing you have the confidence, skills and behavior to manage your health condition while self-efficacy is believing you will succeed in a task, goal. Knowing the stellar reputation of your group, I'm sure you considered this; might be nice to have a sentence about the decision to omit such as patient activation is a somewhat "hot" topic.	
		p. 38, line 18 - colon after wait-list should be a comma	
		p. 41 line 30 - reported should be reports or reporting	
		p. 41 - My significant concerns about measurement of performance bias are noted above	
		p. 42, line 5 - The fact that about half of the trials did not report complete outcome data and did not include attrition data is a much better indicator of the low quality of the behavioral trials than the blinding issue. I'd state this instead.	

Question Text	Reviewer Number	Comment	Authors' Response
		p. 43 - A legend would be nice for Figure 10	
		p. 44 line 31 - add "of" before health coaching	
		p. 45 line 12 - add "s" to finding	
		p. 50. lines 8, 25, and 34 - I may not be reading the table correctly, but I thought that the p values in the bolded Summary (lines 25 and 24) were the overall p value for the pooled estimate. If that is true, then there is an error here: line 8 notes that only the pooled estimate for score of 4 was significant but the p values suggested that score of 4 was not and the estimate for score of 3 was.	
		p. 51 line 9 - "varaibility" has a typo	
		p. 53 lines 15-16 - seems strange to me to group together peers and trained educators	
		p. 53 line 29 - should read with "a score of 1" rather than scores	
		p. 54 line 8 - remove "and"	
		p. 54 line 22 - do you mean video rather than video chat (as in chat thru texts)?	
		p. 56 line 45 - should read "effect of intervention does on change in physical activity" - not on health coaching	
		p. 58 line 32 - monthly coaching for how long?	
		p. 58 lines 43-44 - Again, I'm now doubting that I'm reading the figures right, but if the p values in the bolded Summary (lines 13 and 19 on Figure 22, p. 61) were the overall p value for the pooled estimates, then something is wrong. The text (p. 58 lines 43-44)	

Question Text	Reviewer Number	Comment	Authors' Response
		indicates that the first pooled estimate is sig, but the p noted is 0.51)	
		p. 59 line 41 - Same problem - the text on p. 59 line 41 does not agree with the p value in Figure 21, line 14. Is it significant or not? Looks like it is.	
		p. 64 line 15 - should it say "synthesis FOR this outcome"?	
		p. 65 line 3 - Figure title would more accurately read "Effect of HC on CHANGE IN BMI"	
		p. 65 line 54 - add "participants" after CVD	
		p. 66 line 12 - change "of" to "on" as in effects on BMI	
		p. 66 line 14 - change "or" to "on" in the figure title	
		p. 67 line 19 - Again, the text and figure don't match. Line 19 suggests that the in-person pooled estimate is not significant but Figure 28 notes p of 0.014 (unless you are adjusting the P, which is not stated anywhere)	
		p. 67 line 24 - Figure title would be more accurate if it read "on CHANGE IN BMI"	
		p. 69 line 16 - please make this read "produced ONE OF the largest point estimateS" bc it's not the largest; Varney (2014) and Ma (2013) were both larger.	
		p. 70 lines 38 and 40 - what do the numbers (98), (519 and 626) mean?	
		p. 70 line 46 - Up to this point in the report, behavioral health providers have not been considered/categorized as healthcare providers.	

Question Text	Reviewer Number	Comment	Authors' Response
		Although I disagree with that categorization, it would be better to use language here that is consistent.	
		p. 71 line 24 - drop "groups of" so that it reads "other 2 studies"	
		p. 73 line 20 - The p value of 0.28 does not suggest a trend toward significance as stated on p. 72 line 39.	
		p. 73, lines 38 -39 - Similarly, the text does not agree with the p values on Figure 34. P of 0.94 is not significant (again, if I'm reading the figures correctly) but 0.038 does trend that way.	
		p. 74 line 35 add "s" to element	
		p. 75 line 14 - is this p value correct? Doesn't look that way.	
		p. 75, line 43 - weight loss is not a behavior	
		p. 75, line 57 - As noted above, coaches do not give advice, including motivational advice	
		p. 76 line 6 - add "s" to patient	
		p. 76 line 11 - add "an" before a priori	
		p. 76 line 17 - I'd re-categorize weight/BMI as a clinical outcome	
		p. 76 line 29 - The fact that only 68% were even patient-centered tells you that many were not health coaching interventions.	
		p. 77 line 51 - change "inconsistence" to "inconsistency"	
		p. 78 line 29 - add "on" after "based"	



Question Text	Reviewer Number	Comment	Authors' Response
		p. 78 line 35 - conducting needs a "t"	
		p. 79 line 4 - add "to" after "amenable"	
		p. 79 line 19 - at what time point did the 665 steps/day arise? Is it possible to estimate, average or say in interventions of at least X week duration?	
		p. 79 line 27 - add "per day" after kcal	
		p. 79 line 45 - I'm happy to see this conclusion that HC is likely as effective as other self-management approaches" and it may be useful to add a further sentence that underlines that further work is needed, not only about how it is distinct from other behavioral, patient-focused approaches but that further work is needed to determine when i may be most appropriate, and that clarification studies are needed to determine appropriate background and coach training needed.	
		p. 79 line 46 - chance "in" to "is"	
		p. 79 line 53 - I disagree with that there was "careful quality assessment" - it was indeed very careful and thorough but for biomedical rather than behavioral designs.	
		p. 80 lines 4-6 - It would be nice to highlight that the intervention diversity, although you valiantly attempted to unpack it, it highly problematic in interpreting the results. This seems underplayed to me.	
		p. 80 line 19 - The report doesn't really include number of providers, perhaps you meant number of contacts?	

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		p. 80, line 27 - Drop "certified" as the distinction is	
		meaningless at this point in time.	
		p. 81 line 15 - I'd remove "health coaching-related	
		content" as this implies that the investigators don't	
		really understand what coaching is, and assume it is a content-driven intervention	
		a content-driven intervention	
		p. 81 - Twice in the chart, "non-randomized	
		controlled before-and-after studies" Is noted. Is that	
		not the same as prospective trials (which is also	
		mentioned)?	
		04 11 - 50 11   1   1   1   1   1   1   1   1   1	
		p. 81 line 58 - I'd add that additional research is	
		needed regarding the very definition of coaching.	
		p. 81 - A couple important implications that are not	
		mentioned should be considered. First, the time-	
		course of health coaching trials is quite tricky; people	
		must practice behavior change long enough to	
		adequately demonstrate the subsequent shift in	
		biological measures; short trials (most often funded)	
		make it hard to evaluate longevity and impact of	
		behavior change. Second, as I mentioned above, the	
		fact that participants self-determine their goals means that people are often working on different	
		behaviors and have different outcome goals. Hence,	
		it is challenging to create inclusion criteria that	
		maximizes the capture of potential change. Finally,	
		the conclusions would be another great place to	
		mention that use of biomedical quality ratings for	
		behavioral trials is usually inappropriate, and that UC	
		or wait-lists are often the best controls for behavioral	
		effectiveness trials. In addition, I don't imagine that	
		an ESP would be willing to go here, but the truth is	
		that the focus on RCTs themselves may limit the evaluation of effectiveness when the intervention is	
		driven by patient-preference. Happy to provide refs	
		for this if you'd entertain a comment on such.	

Question Text	Reviewer Number	Comment	Authors' Response
		p. 107 line 37 - I wish you had NA as an option for behavioral trials where it is literally impossible to blind the participants to which condition they are receiving	
		p. 108 - For detection bias, how did you handle self-report instruments in terms of blinding? If the assessment personnel was blinded, but the participants appropriately were not, these could not be blinded either.	
		p. 110 format issue betweens lines 4 and 7	
		Despite my difference in opinions and my many comments, I am grateful for your hard work, and appreciate what you have contributed to this emerging field.	
	4	The greatest Issue I had with the report was the lack of application of the clear description of the intervention that is then required to be applied in the studies. The intervention of Health Coaching was defined, yet included studies didn't have to actually about that predefined intervention. Yet, the study drew conclusions about the effectiveness of Health Coaching, when Health Coaching as it was defined is not even the confirmed intervention. For example, some included studies had NONE of the 3 defined key elements of Health Coaching. An effective definition of an intervention like Health Coaching needs to be clear about not only what it is, but what it	We thank the reviewer for these thoughtful comments. As discussed above, any method for identifying literature for complex behavioral interventions has strengths and limitations. This is even more pronounced when the complex behavioral intervention has not been well defined and there is no consensus on what constitutes key elements of the approach. Such is the case for health coaching. Thus, in close consultation with our key stakeholders and our technical expert panel, we weighed our options for identifying this literature and jointly decided upon use of self-identified interventions. This approach is supported in the literature, including Wolever review:
		isn't. It isn't directive or prescriptive. It isn't predetermined in frequency or agenda by the providers or study administrators. This design implies a deep seated lack of understanding of the principles of Health and Wellness Coaching, besides the 3 determinants discussed, which appeared to be optional. See Wolever, Ruth Q., et al. "A systematic review of the literature on health and wellness coaching: defining a key behavioral intervention in	<ul> <li>(1) Olsen JM, Nesbitt BJ. Health coaching to improve healthy lifestyle behaviors: an integrative review. Am J Health Promot. 2010;25(1):e1-e12</li> <li>(2) Kivela K, Elo S, Kyngas H, Kaariainen M. The effects of health coaching on adult patients with chronic diseases: a systematic review. Patient Educ Couns. 2014;97(2):147-157.</li> </ul>



Question Text	Reviewer Number	Comment	Authors' Response
		healthcare." Global Advances in Health and Medicine 2.4 (2013): 38-57. There is great potential damage by making conclusions about whether Health Coaching is effective or not, when it appears that the intervention	(3) Wolever RQ, Simmons LA, Sforzo GA, et al. A systematic review of the literature on health and wellness coaching: defining a key behavioral intervention in healthcare. Glob Adv Health Med. 2013;2(4):38-57.
		evaluated didn't even meet criteria to be considered health coaching.	Our intent in creating the concordance score was not to characterize interventions as meeting health coaching criteria if these three elements were present. Rather, we
		The International Consortium Health and Wellness Coaches (http://ichwc.org) under the scope of determining eligibility for sitting the National Board exam, requires that coaching sessions on practice logs must be a minimum of 3/4 specifically coaching, and NOT education or instruction. While there was elegant statistical analysis done, I feel decisions made early about what to include in the review did not lead to advancing the understanding of the field or fair assessment of the effectiveness of such heterogenous interventions.	were interested in examining the relationship between concordance with key elements and select outcomes. Thus, a study could contain none of the prioritized elements and still be included. We have expanded our limitations section to more fully capture the heterogeneity of the included studies and the impact this has on our findings.
	5	Thank you for the opportunity to review this research synthesis report. I was very impressed with the rigor and breadth of the report. I believe it has excellent insights for clinical practice (despite the young state of health coaching literature). The area of the report that was lacking (in my opinion) was more robust explanation and strategy around "Concordance." Concordance (which is associated with intervention	Thank you for these comments. We developed the list of key elements and the subsequent concordance score as an exploratory approach to unpacking variability in treatment effects. As described above, these elements were not used as part of the eligibility criteria. We have expanded our limitations section to add more emphasis to the high level of intervention variability in this review.
		fidelity) was loosely and subjectively defined. Three elements were chosen based on the Wolever (2013) article: Patient-centeredness, patient-determined goals, and use of self-discovery. A score of 0 - 4 was assigned, with one element receiving a maximum of two points. The rationale for this was that "(patient-centeredness) was rated as the main driver of coaching effects by our stakeholders." Given the quantitative rigor of this report, this particular decision seems quite subjective. In my clinical experience, patient-centeredness is a pre-requisite of an effective	Reviewer disagreements about presence or absence of key elements were arbitrated in the same way as all other data abstraction elements as described in the methods section. The two reviewers worked to come to consensus. If they could not, then a third reviewer, most often the PI, broke the tie. We, unfortunately, did not track inter-rater reliability between reviewer pairs on these elements.

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		coaching experience, but it is not the most heavily weighted. In fact, the Motivational Interviewing literature shows that counselors/coaches who are effective at relationship building but not effective at focusing sessions on patient-centered goals have less impact on treatment outcomes. Additionally, two reviewers rated the papers for concordance but their inter-rater reliability was not reported. Where they did differ in their ratings, there was no defined process for how differences were reconciled.  I strongly recommend that you include more information about your treatment of Concordance in your methodology and in your conclusions and limitations sections.  My reason for emphasizing this point is this: If the intervention delivered did not adhere to treatment fidelity, you cannot explain outcomes. If something failed to have impact, it may be because that "something" was not accurately delivered. Likewise, if something had impact but not treatment fidelity, you cannot say how the outcome was achieved. If Concordance was more completely and defensibly described, I would have given this review an "excellent" rating.  A few additional comments are included in my uploaded text.  Thank you again for the opportunity to review this paper.	
	7	Overall it is a nice review that provides some interesting data, which have the potential to move the field forward. The biggest concerns I have with the review are twofold. First, there appears to be an underlying assumption that health care providers somehow have training that makes them experts in coaching. Having trained nearly 400 health care providers in coaching, I can veritably say, this is not true. For example, on page 76, the authors write, "all	Thank you for these thoughtful comments and your careful review. We agree that training as a health care provider is not equivalent to training as a health coach. We did not mean to imply so in this report. We systematically captured they type of person delivering the intervention and labeled this as "coach type" but the reviewer is correct that this should be corrected so as not to confound interventionist's discipline (eg, medicine, nursing) with coach training. We



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		delivered by the following: certified health coach,	have modified language throughout the report to reflect this
		study-trained coach, nurse, and a coach with an	distinction.
		unspecified training or discipline." Because one is a	
		nurse or a physician does not make one a coach.	
		This needs to be clarified throughout the text.	
		Relatedly, in the limitations section it needs to be	
		made clear that there really are no examples where	
		trained health professionals who are also certified	
		coaches provide the interventions. This is a	
		significant gap in the literature, and based on the	
		data presented in this review, it appears that more	
		studies need to examine the efficacy of coaching	
		interventions where health care providers trained in	
		health coaching provide the coaching. It would be	
		nice to see this in the implications - what would it look	
		like to move forward effectively in the realm of	
		"innovative and rigorous study designs to explore the	
		central elements that distinguish health coaching	
		from other behavioral counseling and self-	
		management approaches and how these unique	
		elements impact clinical and behavioral outcomes?"	