EVIDENCE REPORT AND EVIDENCE-BASED RECOMMENDATIONS

Chronic Disease Self Management for Diabetes, Osteoarthritis, Post-Myocardial Infarction Care, and Hypertension

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EXECUTIVE SUMMARY

Introduction

Chronic diseases currently affect well over one hundred million Americans. Though chronic diseases are not immediately life threatening, they pose a significant threat to the health, economic status and quality of life for individuals, families and communities.[1, 2] The greatest burden of chronic disease is concentrated in the 65-year and older age group. In 1995, 79% of noninstitutionalized persons who were 70 years and older reported having at least one of seven of the most common chronic conditions: arthritis, hypertension, heart disease, diabetes, respiratory diseases, stroke, and cancer.[1] Demographic trends portend alarming increases in the next 20 years.

There is a growing enthusiasm for self-management programs, either as stand alone program or as integral components of chronic care models, in controlling and preventing chronic disease complications.[3-7] Despite this enthusiasm, there is no agreed definition of what constitutes a "chronic disease self-management program" nor is there agreement on which elements of self management programs are most responsible for any beneficial effects.

We therefore sought to use empirical data from the literature to address the following research questions posed by the Centers for Medicare and Medicaid Services (CMS).

1. Do these programs work?
2. Are there features that are generalizable across all diseases?
3. Does this intervention belong in the medical care system?
4. Define chronic disease self-management and distinguish between it and disease management.
5. What is the role or potential of technology?

6. What is the impact of chronic disease self-management programs on quality of life, health status, health outcomes, satisfaction, pain, independence, and mental health (e.g., depression, emotional problems)?
7. To what extent does self-management educate a patient on how to care for himself/herself (e.g., take medications appropriately, consult with a physician when necessary, etc.)?
8. What is the patient's retention of self-management skills after the intervention? Is a follow-up intervention needed at some point?
9. How does the approach for self-management differ for people with multiple chronic diseases?
10. Is a generic self-management approach preferable to a disease-by-disease approach?
11. Should this intervention be targeted to a subset of the population or available to everyone? Are there particular chronic conditions that should be addressed (e.g., diabetes, arthritis, stroke, cancer, Parkinson's, hypertension, dyslipidemia)?
12. What is the role of the physician? Can physicians be used to reinforce learning?
13. Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?
14. Delivery mechanism: What do we know about whom (which provider type? trained lay person?) should deliver this service? Do we know which care settings have proven effective (e.g., physician's office, senior center, other community or clinical settings)?

To address these questions, we focused on evaluating the effect of self-management programs for the four chronic conditions most commonly studied in controlled trials of older adults: osteoarthritis, diabetes mellitus, hypertension, and post myocardial infarction.

Methods

Conceptual Model

In order to avoid the premature loss of potentially relevant studies, we broadly defined "chronic disease self-management" as a systematic intervention that is targeted towards patients with chronic disease to help them to actively participate in either or both of the following activities: self-monitoring (of symptoms or of physiologic processes) or decision-making (managing the disease or its impact based on self-monitoring). All interventions included in this study attempt to modify patient behavior to reach specific goals of chronic disease self-management.

We attempted to understand the characteristics particular to chronic disease self-management programs that may be most responsible for their effectiveness. Based on the literature and expert opinion, we postulated five hypotheses regarding effectiveness of chronic disease self-management programs:

1 Patients who receive interventions tailored to their specific needs and circumstances are likely to derive more benefit than those receiving interventions that are generic. (Tailored)

2 Patients are more likely to benefit from interventions received within a group setting that includes others affected by the same condition than they are to benefit from an intervention that was provided by other means. (Group Setting)

3 Patients who are engaged in a cycle of intervention followed by some form of individual review with the provider of the intervention are more likely to derive benefit than from interventions where no such review exists. (Feedback)

4 Patients who engage in activities using a psychological intervention are more likely to derive benefit than from interventions where there is no psychological emphasis. (Psychological)

5 Patients who receive interventions directly from their medical providers are more likely to derive benefit than those who received interventions from non-medical providers. (Medical Care)

Outcome measures

For the diabetes studies we used hemoglobin A1c, fasting blood glucose, and weight as outcomes. For osteoarthritis, we used measures of pain and function. As would be expected, we used systolic and diastolic blood pressure for hypertension. For post MI care, we used return to work and mortality. For all conditions, we also collected intermediate outcomes such as knowledge, feeling of self-efficacy, and health behaviors that are postulated to be related to clinical outcomes. We separately assessed studies reporting costs.

Databases for Literature Search

To identify existing research and potentially relevant evidence for this report we searched a variety of sources including the Cochrane Library (containing both a database of systematic reviews and a controlled-trials register), the *Assessment of Self-Care Manuals* published by the Oregon Health Sciences University (March 2000), and *An Indexed Bibliography on Self-Management for People with Chronic Disease* [8] published by the Center for Advancement of Health (CAH). In addition Medline, PsycInfo, and Nursing and Allied Health databases were search.

Seventy-three other review articles on disease management were obtained; each review discussed at least one intervention aimed at chronic disease self-management. We retrieved all relevant documents referenced. We also contacted experts in the field and asked for any studies

that were in press or undergoing review. Finally, we exchanged reference lists (but not analyses or results) with a leading east coast university also performing a review of chronic disease self-management programs, but not limited to older adults.

Article Selection and Data Abstraction

Article selection, quality assessment, and data abstraction were done in standard fashion by using two trained physician reviewers working independently; disagreements were resolved by consensus or third-party adjudication.

Statistical Analyses

We answered many of the research questions through meta-analysis. We conducted separate meta-analyses for each of the four medical conditions. We included all controlled trials that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group. The majority of our outcomes were continuous and we extracted data to estimate effect sizes for these outcomes. For each pair of arms, an unbiased estimate[9] of Hedges' g effect size[10] and its standard deviation were calculated. A negative effect size indicates that the intervention is associated with a decrease in the outcome at follow-up as compared with the control or usual care group.

Because follow-up times across studies can lead to clinical heterogeneity, we excluded from analysis any studies whose data were not collected within a specified follow-up interval chosen based on clinical knowledge.

For each condition and outcome, we conducted the same analysis. We first estimated a pooled random effects estimate[11] of the treatment effect and a pooled effect size for continuous outcomes across all studies and its associated 95% confidence interval. For each of the original five hypotheses stated above, study arms either met the hypothesis (a "yes") or did not (a "no")

and thus, no missing values exist. For each hypothesis, a simple stratified analysis would have produced a pooled estimate of the treatment effect for all the “yes” study arms together, and a pooled estimate for all the “no” study arms together. To facilitate testing the difference between the two pooled estimates, we constructed these estimates using meta-regression in which the only variables in the regression were a constant, and an indicator variable equal to one if the study arm met the hypothesis and zero if the study arm did not. For some outcomes and hypotheses, all study arms were either "yes" or "no." In this case, we could not fit a model.

As an overall test of the hypotheses, we combined the pain outcomes from osteoarthritis studies, hemoglobin A1c outcomes from diabetes studies, and systolic blood pressure outcomes from hypertension into one analysis using effect size and fit the five separate regressions as above. We also fit a sixth regression that had a constant and all five-indicator variables for the separate regressions included.

Sensitivity Analyses

Within each regression, and especially in the combined analysis, our primary analysis ignored the fact that individual studies had multiple intervention arms and thus could contribute more than one treatment effect to the analysis. The correlation between treatment effects within the same study, due to the fact the each intervention arm was compared to the same control or usual care arm, was ignored in this analysis. Our sensitivity analyses consisted of refitting the meta-regression models using a two-level random effects model that contains a random effect at the study level, as well as one at the arm level. This hierarchical approach controls for the correlation within arms in the same study. None of these sensitivity analyses results differed markedly from that of the primary analysis.

Post Hoc Analyses

We presented the results of the above analyses to a group of experts in chronic disease self-management. Based on this presentation, members of this group suggested a series of additional analyses exploring other possible mechanisms for an effect of self-management programs. These included classifying the studies according to categories proposed in the RE-AIM Model,[12] classifying the studies according to potential "essential elements" proposed by this group,[13] assessing whether the effectiveness of self-management programs varied by severity of illness, and assessing whether interventions more likely to improve the "intermediate variables," such as knowledge and perception of self-efficacy, were more likely to improve health outcomes

Results

Question 1. Do these programs work?

Question 2. Are there features that are generalizable across all diseases?

Question 6. What is the impact of chronic disease self-management programs on quality of life, health status, health outcomes, satisfaction, pain, independence, mental health (e.g., depression, emotional problems)?

Question 10. Is a generic self-management approach preferable to a disease-by-disease approach?

These questions are all related and were the focus of our meta-analysis. We first present a disease-by-disease assessment of the evidence for efficacy, then our assessment of generalizable or generic elements of a self-management program.

Diabetes

There were 14 comparisons from 12 studies that reported hemoglobin A1c outcomes. In an overall analysis of the effectiveness of chronic disease self-management programs, these studies reported a statistically and clinically significant pooled effect size of -0.45 in favor of the intervention (95% CI: (-0.26, -0.63)). The negative effect size indicates a lower hemoglobin A1c in the treatment group as compared to the usual care or control group. An effect size of –0.45 is equal to a reduction in hemoglobin A1c of about 1.0. For change in weight, there were 10 comparisons from 8 studies. There was no statistically significant difference between change in weight in the intervention and control groups (effect size of -0.05; 95% CI:(-0.12, 0.23)). There were 10 comparisons from 9 studies that reported fasting blood glucose outcomes. The pooled effect size was -0.41 in favor of the intervention (95% CI: (-0.23, -0.60)). This effect size equates to a drop in blood glucose of 1 mml/l.

Our assessment of publication bias revealed likely publication bias in studies reporting hemoglobin A1c outcomes. Therefore, our results regarding efficacy of chronic disease self-management programs for improving hemoglobin A1c must be interpreted with caution.

Osteoarthritis

For both pain and function outcomes there were 10 comparisons from 7 different studies. The pooled results did not yield any statistically significant differences between intervention and control groups (pooled effect sizes of -0.04 and -0.01 for pain and function respectively). Our assessment of publication bias did not yield any evidence of publication bias.

Hypertension

For hypertension there were 23 comparisons from 14 studies that reported systolic and diastolic blood pressure changes. The overall pooled result of the chronic disease self-

management programs was a statistically and clinically significant reduction in systolic and diastolic blood pressure (effect size for systolic blood pressure -0.32; 95% CI: (-0.50, -0.15); effect size for diastolic blood pressure -0.59; 95% CI: (-0.81, -0.38)). An effect size of 0.32 is equivalent to a change in blood pressure of 3.5 mm of mercury, the corresponding value for an effect size of 0.59 is 6.5 mm of mercury. In our assessment of publication bias, there was evidence of publication bias. Therefore our pooled result favoring chronic disease self-management programs for hypertension must be viewed with caution.

Post Myocardial Infarction Care

There were 9 studies that reported mortality outcomes. There was no effect of chronic disease self management programs on improving mortality (pooled relative risk 1.04; 95% CI: (0.56, 1.95)). For return to work there were 10 comparisons from 8 studies. The pooled relative risk did not show any difference between groups (relative risk 1.02; 95% CI: (0.97, 1.08)). Our assessment of publication bias showed evidence of publication bias for the mortality outcome but not the return to work outcome.

Tests of hypothesis of elements essential to chronic disease self-management efficacy

Other than an increased effectiveness seen in hypertension studies reporting systolic blood pressure outcomes that used tailored interventions, there were no statistically significant differences between interventions with or without the 5 features hypothesized to be related to effectiveness (tailoring, use of group setting, feedback, psychological component, and medical care). Indeed, many of the effects seen were inconsistent across outcomes within the same condition. For example, in hypertension studies, for the hypothesis “use of a group setting,” there was a greater than 50% increase in the effect size for improvement in systolic blood

pressure, but only a 5% increase in the effect size for improvement in diastolic blood pressure (with neither result reaching statistical significance).

Our "across condition" analysis shows effect sizes that, in general, go in the direction of supporting increased effectiveness associated with the use of these intervention features, however none of the differences are statistically significant.

Post Hoc Analyses

Our “post hoc” tests of possible “essential elements” of chronic disease self-management programs was unrevealing. The RE-AIM theory[12] suggests that the following components: one-on-one counseling interventions (individual), group sessions (group), telephone calls (telephone), interactive computer-mediated interventions (computer), mail interventions (mail) and health system policies (policy 1 and policy 2) led to positive outcomes. With few exceptions, there were no results that were statistically significant. An exception is the result for the use of one-on-one counseling sessions, which did show a statistically significant increased effect size when used.

For the “Essential Elements of Self-management Interventions” evaluation, we did not find as much variation among studies and components as is necessary for optimal power in the analysis. Most of the studies scored positively for “problem identification and solving,” and did not score positively for the “ensuring implementation component.” Given these data, we did not find evidence to support either any one of these three broad “essential elements” as necessary, nor some threshold (such as two out of three) in terms of efficacy. This was not an optimal test of these hypotheses due to the lack of variation in the data.

Our analysis of the effect of self-management intervention on "intermediate variables" such as knowledge and self-efficacy did not produce consistent results supporting an effect in the expected direction.

Lastly, it was suggested we stratify by baseline patient severity. Only the assessment of hemoglobin A1c demonstrated an increased effect size in patients who had higher (worse) value of hemoglobin A1c at baseline, and this difference did not quite reach statistical significance.

Question 3. Does this intervention belong in the medical care system?

Whether chronic disease self-management belongs in the medical care system or in the community is a decision that needs to be made by policy makers, based on many factors. One of the first hypotheses we tested was whether patients who receive interventions directly from their medical providers are more likely to have better outcomes than those who received interventions from non-medical providers; no effect was found. Of the controlled studies that made it into our meta-analysis, no studies of osteoarthritis or hypertension used medical providers in their self-management interventions. Regarding diabetes, one intervention used medical providers; the results of this intervention were not significantly different than those using lay leaders. One post-myocardial infarction intervention used medical providers; the effects on mortality and return to work were not statistically different from those of the other interventions.

Question 4. Define chronic disease self-management and distinguish between it and disease management.

For purposes of this review, we initially defined chronic disease self-management broadly as a systematic intervention that is targeted towards patients with chronic disease to help them to actively participate in either or both of the following activities: self monitoring (of

symptoms or physiologic processes) or decision-making (managing the disease or its impact based on self-monitoring). Our analytic attempts to "define" chronic disease self-management by identifying the components most responsible for the success of the program were unsuccessful.

The draft evidence report was presented to a group of experts in chronic disease self-management at a meeting convened by the Robert Wood Johnson Foundation on December 14, 2001. The panel's aim was to focus on interventions offered to patients who need a more intense level and type of self-management support. They agreed that all self-management programs should address the following three areas.

Disease, medication and health management. While patients need medical information about their particular disease (diabetes, arthritis, asthma, etc.), the majority of the content in most successful self-management programs emphasized generic lifestyle issues such as exercise, nutrition, and coping skills. More disease-specific medication-specific information can be useful, but such information rarely constitutes more than 20 percent of the content of programs.

Role management. Patients benefit from programs that help them maintain social support, connection to work and family, and normal functions of daily life.

Emotional management. Programs should encompass managing depression and stress, adaptation to change, and maintaining interpersonal relationships.

A monograph authored by Dr. Jesse Gruman (Center for the Advancement of Health, 2002) summarized the discussions from this meeting. The experts concluded that the essential elements of self-management programs should include the following:

1. Problem-solving training that encourages patients and providers to identify problems, identify barriers and supports, generate solutions, form an individually tailored action plan, monitor and assess progress toward goals, and adjust the action plan as needed.
2. Follow-up to maintain contact and continued problem-solving support, to identify patients who are not doing well and assist them in modifying their plan, and to relate the plan to the patient's social/cultural environment.
3. Tracking and ensuring implementation by linking the program to the patient's regular source of medical care and by monitoring the effects of the program on the patient's health, satisfaction, quality of life, and health system quality measures.

The experts also recommended that any chronic disease self-management program be composed of two tiers to accommodate the wide variety of patients with chronic conditions. The first tier would include a low-intensity intervention designed to reach mass audiences and open to anybody with a particular illness. The second tier would include a high-intensity intervention targeted to people who require one-on-one support and case management. This program could be offered to those who have not successfully managed their condition with the minimal support of tier #1, those who have complicated conditions, and those whose life circumstances or conditions change significantly.

Question 5. What is the role or potential of technology?

The advent of new technologies makes communication between patients, providers, and others more convenient than ever. However, none of the randomized controlled studies on chronic disease self-management for our study conditions in older patients used email or the Internet. Thus, we were not able to quantitatively assess the impact of these technologies. A

recently reported study of back pain in middle aged adults reported modest improvements in outcomes and costs for subjects randomized to a physician-moderated "email discussion group" and educational material compared to a control group that received a magazine subscription. This study suggests that incorporating these technologies into future randomized studies would be a worthwhile endeavor.

Question 7. To what extent does self-management educate a patient on how to care for himself/herself (e.g., take medications appropriately, consult with a physician when necessary, etc.)?

Most CDSM studies that assess knowledge and self-efficacy reported beneficial improvements. Most studies did NOT measure whether medications were taken appropriately or "necessary" physician visits were made. The two studies that did assess compliance were hypertension studies. One had a borderline beneficial overall result; the other reported a significant beneficial result. One study was based on a conceptual model that specifically considered that changing medication-taking behavior was going to be easier than changing diet behavior or other such behaviors. This study did not actually measure compliance, but rather measured "commitment to taking medications" and showed that this differed between intervention and controls and that it was one of only three variables among those tested to be associated with significant changes in blood pressure (the other two were ""belief in severity of the disease" and "beliefs in efficacy of therapy"). Many studies assessed utilization, but none assessed whether the utilization was necessary.

Question 8. What is the patient's retention of self-management skills after the intervention? Is a follow-up intervention needed at some point?

We were unable to find studies that actually included a "follow-up intervention" which incorporated refresher skills on self-management. In light of this, we used a meta-regression model to test whether self-management interventions that provide follow-up support led to better results than those that did not. We classified interventions that maintained contact with the patient through contracts, provider feedback, reminders, peer support, material incentives, or home visits as including "follow-up support." Of the interventions which could be included in our meta-analyses, 19 had "follow-up support" while 28 did not. Pooled results were not statistically different between the two groups.

Question 9. How does the approach for self-management differ for people with multiple chronic diseases?

We found no evidence on this topic.

Question 11. Should this intervention be targeted to a subset of the population or available to everyone? Are there particular chronic conditions that should be addressed (e.g., diabetes, arthritis, stroke, cancer, Parkinson's, hypertension, dyslipidemia)?

We were able to quantitatively assess the effects of chronic disease self-management programs on patients with diabetes, osteoarthritis, and hypertension. In addition, we were able to pool results for post myocardial infarction programs. There were insufficient studies on stroke, cancer, Parkinson's and dyslipedemia to allow pooling.

In an attempt to assess whether chronic disease self-management programs were more effective for more severe patients, we undertook a post-hoc quantitative analysis. Two clinicians independently categorized each diabetes and osteoarthritis program as focusing on either more severe or less severe patients. The clinicians were unable to categorize the hypertension and post- MI programs in such a fashion, due to the lack of heterogeneity of the patients. In the diabetes analysis, there was no statistical difference between the effectiveness of programs targeted to more severe and less severe patients, in terms of change in hemoglobin A1c or weight. For osteoarthritis studies, there was no statistical difference in change in pain or functioning.

Question 12. What is the role of the physician? Can physicians be used to reinforce learning?

Out meta-analysis did not reveal any statistically significant differences supporting the role of physicians at enhancing the efficacy of chronic disease self-management programs.

Question 13. Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?

A total of 19 clinical trial studies were identified in this review of the economic impact of Chronic Disease Self-Management (CDSM). These include 9 studies on diabetes, 4 studies on osteoarthritis, one study on hypertension, two on post-myocardial infarction, and three non-disease-specific programs for chronically ill patients. They represented only a subset of possible strategies for CDSM. Thus our economic review has limited generalizability beyond the studied interventions.

Costs of the intervention were rarely reported and health care costs as an outcome of the intervention were rarely studied. Changes in health care utilization were seldom reported, and in many cases only studied on a limited scale (not including all types of services). The follow-up period was short, while many outcomes will not be evident for many years (e.g., rigid metabolic control may result in delay or prevention of diabetic complications, but only after several years).

Among the four diseases reviewed, the programs to promote self-management with osteoarthritis patients have the best economic information and most consistently report reductions in health care utilization and costs, even to the point of cost-savings. Such findings are compatible with observational studies.[14-16] Programs for diabetic patients have mixed results, and overall are weaker in the economic information they report. There is only one hypertension program identified that include any economic information, and the information provided does not allow us to adequately judge cost-effectiveness of the program. The two reviewed MI studies both lacked a rigorous collection of economic data, but the limited evidence presented suggests that home-based rehabilitation programs could potentially be a cost-effective alternative to group rehabilitation or standard care. As for the three general, non-disease-specific programs, two RCTs and two observational studies reported that low-cost, community-based CDSM programs may potentially be cost-saving.

Limitations

Despite finding evidence that CDSM programs have a clinically and statistically significant beneficial effect on some outcomes, we were unable to discern which elements of CDSM programs are most associated with success. This may have been because we did not test the right hypotheses regarding CDSM elements, or because key variables describing these components were either not recorded adequately or not recorded at all in the published articles,

or that the individual components themselves each have relatively weak effects. We considered contacting original authors for additional information regarding their interventions, but rejected this due to time and resource constraints. Furthermore, our experience has been that any study published more than a few years ago has a much lower likelihood for getting a favorable response to such a request. In addition, we may have lacked the statistical power, due to the small number of studies available, to discern the reasons for the relatively small amount of heterogeneity in the study results. We note that the preceding challenges are common to all studies of complex, multicomponent interventions, and these challenges did not prevent us from detecting important differences in the effectiveness of interventions for prevention of falls[17] or increasing the use of cancer screening and immunizations.[18]

An additional primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in self-management (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and their relationship to bias, we did not attempt to use other criteria.

As previously discussed, we did find evidence of publication bias in hemoglobin A1c, mortality, and systolic and diastolic blood pressure outcomes in diabetes, post-myocardial infarction care, and hypertension, respectively. Therefore, the beneficial results that we report in our pooled analysis need to be considered in light of the possible existence of unpublished studies reporting no benefit.

Conclusions

1. Chronic disease self-management programs probably have a beneficial effect on some, but not all, physiologic outcomes. In particular, we found evidence of a statistically significant and clinically important benefit on measures of blood glucose control and blood pressure reduction for chronic disease self management programs for patients with diabetes and hypertension, respectively. Our conclusions are tempered by our finding of possible publication bias, favoring beneficial studies, in these two clinical areas. There was no evidence of a beneficial effect on other physiologic outcomes such as pain, function, weight loss, and return to work.

2. There is not enough evidence to support any of the proposed elements as being essential to the efficacy of chronic disease self-management programs. More research is needed to try and establish the optimum design of a chronic disease self-management program, and whether or not this differs substantially depending on the particular chronic disease or characteristics of the patient.

3. While no randomized studies of chronic disease self-management programs for older adults assessed the use of email or the Internet, one recently reported randomized study of email use in the self-management of middle aged adults with back pain was sufficiently promising to warrant testing such interventions for chronic disease self-management in the Medicare population.

4. There is no evidence to conclusively support or refute the role of physician providers in chronic disease self-management programs for older adults.

5. The evidence is inconclusive but suggests that chronic disease self-management programs may reduce health care use.

RECOMMENDATIONS

1. There is sufficient evidence to support a pilot program promoting chronic disease self-management programs for older adults.

2. However, before implementing such a pilot program, additional work is needed to optimally define the essential elements of such programs, and whether they vary by condition or patient characteristic. It is more than likely that any successful chronic disease self-management program will need to be delivered in the context of an organized system of care, or else external to the traditional solo or small group practice physician.

INTRODUCTION

Chronic diseases are conditions that are usually incurable. Although often not immediately life threatening, they pose significant burdens on the health, economic status, and quality of life for individuals, families, and communities.[1] In 1995, seventy-nine percent of noninstitutionalized persons who were 70 years or older reported having at least one of seven of the most common chronic conditions affecting this age group: arthritis, hypertension, heart disease, diabetes, respiratory diseases, stroke, and cancer.[1]

Of these seven conditions, arthritis is most prevalent, affecting more than 47 percent of individuals 65 years and older.[19] Hypertension affects 41 percent of this population while 31 percent have some form of heart disease, of which ischemic heart disease and a history of myocardial infarction are major components. Diabetes affects approximately 10% of persons 65 years and older and increases the risk for other chronic conditions, including ischemic heart disease, renal disease, and visual impairment.[19]

Life-altering disability is a frequent consequence of chronic disease. Of the seven conditions listed above, arthritis is the leading cause of disability.[2] In 1995, 11 percent of noninstitutionalized persons who were 70 years or older reported arthritis as a cause of limitation in their activities of daily living. Heart disease was reported by four percent, while 1.5 percent reported diabetes as a cause of functional limitation.[2]

The proportion of Americans who are 65 years or older is rising steadily. In 1997, thirteen out of every 100 Americans were 65 years or older. Demographers predict this proportion will increase to 20 out of 100 by the year 2030, or approximately 70 million people.

Within this age-group, 8.5 million people will be over 85 years old, more than double the 1997 estimates.[20]

Given these demographic projections, the prevalence of chronic disease and its related costs will also increase dramatically. Therapies for conditions such as osteoarthritis, heart disease, and diabetes have improved considerably over the past 20 years. For example, evidence suggests that exercise programs improve symptoms and reduce disability in individuals with osteoarthritis;[21] modest blood pressure control reduces the incidence of myocardial infarction and stroke;[22] and improved control of blood glucose significantly reduces the incidence of diabetes, complications including neuropathy, renal disease, and blindness.[23, 24]

There is a growing conviction that self-management will be an important component of controlling and preventing illness complications. Studies of condition-specific self-management interventions have been used to evaluate the benefits of particular interventions. However, one difficulty in drawing conclusions from this literature is that the interventions being evaluated often consist of more than one component, making it difficult to identify what caused the intervention as a whole to succeed or fail.

This evidence report was commissioned by the Centers for Medicare & Medicaid Services (CMS) to examine the evidence regarding the effectiveness of chronic disease self-management programs and to assess which components may be most crucial to success. More specifically, this report reviews evidence from controlled trials of chronic disease self-management programs for four of the most common conditions of older adults: diabetes, osteoarthritis; post-myocardial infarction care; and hypertension. Our charge was to report the evidence regarding the following key questions specified by CMS:

1. Do these programs work?
2. Are there features that are generalizable across all diseases?
3. Does this intervention belong in the medical care system?
4. Define chronic disease self-management and distinguish between it and disease management.
5. What is the role or potential of technology?
6. What is the impact of chronic disease self-management programs on quality of life, health status, health outcomes, satisfaction, pain, independence, mental health (e.g., depression, emotional problems)?
7. To what extent does self-management educate a patient on how to care for himself/herself (e.g., take medications appropriately, consult with a physician when necessary, etc.)?
8. What is the patient's retention of self-management skills after the intervention? Is a follow-up intervention needed at some point?
9. How does the approach for self-management differ for people with multiple chronic diseases?
10. Is a generic self-management approach preferable to a disease-by-disease approach?
11. Should this intervention be targeted to a subset of the population or available to everyone? Are there particular chronic conditions that should be addressed (e.g., diabetes, arthritis, stroke, cancer, Parkinson's, hypertension, dyslipidemia)?
12. What is the role of the physician? Can physicians be used to reinforce learning?

13. Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?
14. Delivery mechanism: What do we know about whom (which provider type? trained lay person?) should deliver this service? Do we know which care settings have proven effective (e.g., physician's office, senior center, other community or clinical settings)?

METHODS

We synthesize evidence from the scientific literature on effectiveness of chronic disease self-management programs, using the evidence review and synthesis methods of the Southern California Evidence-Based Practice Center, an Agency for Healthcare Research and Quality—a designated center for the systematic review of literature on the evidence for benefits and harms of health care interventions. Our literature review process consisted of the following steps:

- Develop a conceptual model (also sometimes called an evidence model or a causal pathway).
- Identify sources of evidence (in this case, sources of scientific literature).
- Identify potential evidence.
- Evaluate potential evidence for methodological quality and relevance.
- Extract study-level variables and results from studies meeting methodological and clinical criteria.
- Synthesize the results.

CONCEPTUAL MODEL

There is no standard definition of what constitutes a chronic disease self-management program. Indeed, the second key question we were assigned seeks to define essential components empirically. Still, we needed to start with some initial definition in order to target our literature search. Therefore, for this review, we defined "chronic disease self-management" broadly as a systematic intervention that is targeted towards patients with chronic disease to help them actively participate in either or both of the following activities: self monitoring (of

symptoms or of physiologic processes) or decision-making (managing the disease or its impact based on self-monitoring).

Figure 1 represents a simple conceptual model of how self-management influences patient outcomes. Patient behavior describes all that patients do to self-manage their chronic diseases. All interventions included in this study attempt to modify patient behavior to reach specific goals of chronic disease self-management.

Traditional behavior-change intervention components

Education**.** Educational efforts can be directed toward an individual, group, or entire community. Pamphlets and posters can raise awareness among older adults or staff members at senior centers and nursing homes. More intense educational interventions include one-on-one counseling.

Psychological. Psychological efforts include counseling, cognitive-behavioral therapy, relaxation training, and emotional support groups.

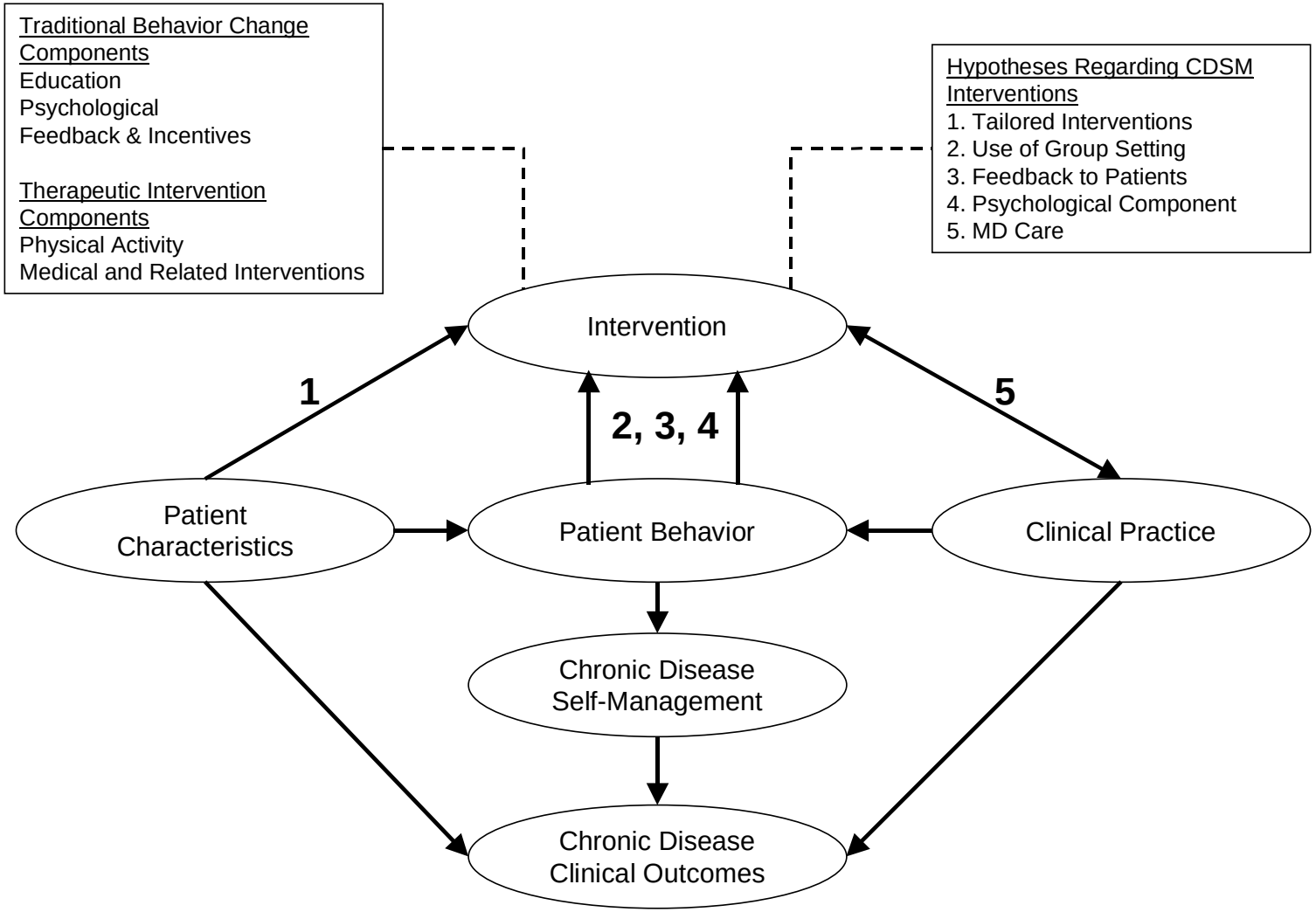
Feedback & Incentives include clinical reviews with patients, contracts, provider feedback, reminders, diaries, goal setting instruction, and material/ financial incentives.

Intervention components aimed at particular physiologic targets include:

Physical Activity includes non-physiotherapy activity, for example walking, cycling, and aerobic movements. Physical activity also includes training geared specifically towards balance, strength, or gait, for example tai chi or tailored physical therapy.

Medical and Related Interventions include interventions such as medication therapy, blood pressure monitoring, and dietary monitoring.

Figure 1. Conceptual Model



Interventions may be modified to account for specific patient characteristics, which result in individualized intervention programs. In this way, the relevance of interventions is enhanced and patients have greater opportunity to be more personally engaged than with generalized programs. Programs that utilize intervention components such as group programs, feedback, or psychological approaches may have greater impact than those programs lacking such components. Programs using approaches more likely to be engaging may therefore enhance the level of patient commitment and effort. These programs are also likely to provide more opportunity for emotional support, both formally and informally, which may address a critical need of patients who struggle with chronic disease conditions. Interventions that work within the context of a clinical practice or are delivered by physicians who are otherwise engaged in the study participants' care may be more relevant and require potentially a greater investment on the part of patients, resulting in increased likelihood of behavior change.

Hypotheses

Of key importance to both CMS and providers is what the essential elements of chronic disease self-management programs seem to be. In this analysis, we attempt to understand the characteristics particular to chronic disease self-management programs that may be most responsible for their effectiveness. This analysis was undertaken to help answer CMS's secondary question, "Are there features that are generalizable across all diseases?" We developed five hypotheses regarding effectiveness (terms in parentheses relate to terms used in evidence tables). These five hypotheses operate on the areas indicated in the conceptual model with the corresponding number.

1. Patients who receive interventions tailored to their specific needs and circumstances are likely to derive more benefit than those receiving interventions that are generic. (Tailored)
2. Patients are more likely to benefit from interventions received within a group setting that includes others affected by the same condition than they are to benefit from an intervention that was provided by other means. (Group Setting)
3. Patients whose intervention is followed by some form of individual review with the provider of the intervention are more likely to derive benefit than patients whose interventions involve no such review. (Feedback)
4. Patients are more likely to derive benefit from activities that use a psychological intervention than from interventions where there is no psychological emphasis. (Psychological)
5. Patients who receive interventions directly from their medical providers are more likely to derive benefit than those who received interventions from non-medical providers. (MD Care)

IDENTIFICATION OF LITERATURE SOURCES

We used the sources described below to identify existing research and potentially relevant evidence for this report. We searched each source for articles specific to the four conditions of interest: diabetes, osteoarthritis, myocardial infarction, and hypertension. We chose these conditions because each had a significant quantity of published literature and each is highly prevalent in older adults. (Because of these criteria we did not search for literature on

conditions with an extensive body of chronic disease self-management literature, such as rheumatoid arthritis or asthma, as both of these are of low frequency in older adults.)

Cochrane Collaboration

The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of heath-care interventions. The Cochrane Library contains both a database of systematic reviews and a controlled-trials registry. The library receives additional material continually to ensure that reviews are maintained and updated through identification and incorporation of new evidence. The Cochrane Library is available on CD-ROM by subscription. The Cochrane Library contained 15 reports on chronic disease self-management; we obtained all studies referenced therein.

Oregon Health Sciences University

The Evidence-based Practice Center (EPC) at the Oregon Health Sciences University published the *Assessment of Self-Care Manuals* in March 2000. The Oregon EPC systematically searched the scientific literature for evidence that self-care manuals produce changes in a variety of outcomes for health care consumers. We scanned the reference list and ordered relevant articles.

In addition, the Oregon EPC sent a brief description of the preliminary review process for a projected titled "Diabetes Self-Management Programs: Medical Guidelines and Patient Self-Monitoring." This document included abstracts on over 20 studies and a list of 13 review articles on diabetes self-management. We ordered all relevant publications.

Center for Advancement of Health

The Center for Advancement of Health (CAH) in association with the Group Health Cooperative of Puget Sound, recently published *An Indexed Bibliography on Self-Management for People with Chronic Disease*. The role of the Center is to promote widespread acceptance and application of an expanded view of health that recognizes psychological and behavioral factors. The bibliography contained abstracts from over 400 journal articles, from 1980 to the present, covering 18 chronic diseases and conditions. We ordered all relevant publications.

Library Search

In addition to obtaining references and materials from the above sources we conducted a library search for all studies published (subsequent to) the CAH bibliography,[8] using the search terms listed below.

Medline, PsycInfo and Nursing and Allied Health databases were the primary sources of citation information. Searches covered 1980 to 1995, although relevant articles from earlier dates were included. The major search strategy consisted of keyword searches using a combination of descriptors to focus the search on pertinent topical areas. Terms representing each of the chronic diseases included in the bibliography were combined with a set of other keyword terms that were likely to identify the types of articles that met inclusion criteria. The following diseases were searched: *Arthritis, Chronic Illness, Diabetes, Heart Disease,* and *Hypertension*. Keywords used in combination with disease names included *Anxiety, Behavior, Compliance, Coping , Depression , Disability, Exercise, Family, Isolation, Modeling, Nutrition, Patient Education, Patient Satisfaction, Problem-Solving, Relaxation, Self-care ,*and *Social Support*.

Related topics of interest were also searched by keyword, such as interactive video, computer interventions, telephone intervention, media, practice redesign, case management, patient provider interaction and illness model. Articles covering a number of different illnesses or behaviors were sometimes identified by one particular keyword in a database. For instance, many types of pertinent self-care behaviors would be included within the keyword "compliance," but not all articles retrieved under "compliance" would be relevant to chronic illness. Thus of articles retrieved with such a search were reviewed for the subset of articles pertinent to chronic illness management.

Previous Systematic Reviews

Sources using the aforementioned, we identified 73 previously completed reviews relevant to this project (see Table 1). Each review discusses at least one intervention aimed at chronic disease self-management. We retrieved all relevant documents referenced in these publications.

Table 1. Review Articles

Review: Self-management education for adults with asthma improves health outcomes. *Evidence-Based Medicine.* 1999;4:15. Rec #: 740

ACP Journal Club. Review: Several interventions reduce complications in type 2 diabetes mellitus. *ACP J Club.* 1998;128:30. Rec #: 2577

Anderson BJ, Auslander WF. Research on diabetes management and the family: A critique. *Diabetes Care.* 1980;3:696-702. Rec #: 2220

Assal JP, Muhlauser I, Pernot A, Gfeller R, Jorgens V, Berger M. Patient education as the basis for diabetes care in clinical practice and research. *Diabetologia.* 1985;28:602-613. Rec #: 2104

Blumenthal J A, Thyrum E T, Gullette E D, Sherwood A, Waugh R . Do exercise and weight loss reduce blood pressure in patients with mild hypertension? *N C Med J.* 1995;56(2):92-5. Rec #: 753

Broderick J E. Mind-body medicine in rheumatological disease. *Rheumatic Disease Clinics of North America.* 1999. Rec #: 609

Brown S A . Meta-analysis of diabetes patient education research: variations in intervention effects across studies. *Res Nurs Health.* 1992;15(6):409-19. Rec #: 759

Brown S A . Studies of educational interventions and outcomes in diabetic adults: a meta-analysis revisited. *Patient Educ Couns.* 1990;16(3):189-215. Rec #: 760

Table 1. Review Articles

Brown SA. Effects of educational interventions in diabetes care: a meta-analysis of findings. *Nurs Res.* 1988;37:223-230. Rec #: 2090

Brownell KD, Kramer FM. Behavioral management of obesity. *Medical Clinics of North America.* 1989;73:185-201. Rec #: 2642

Cassem NH, Hacket TP. Psychological rehabilitation of myocardial infarction patients in the acute phase. *Heart Lung.* 1973;2:382-38. Rec #: 2409

Clark N M . Asthma self-management education. Research and implications for clinical practice. *Chest.* 1989;95(5):1110-3. Rec #: 763

Clark N M, Becker M H, Janz N K, Lorig K, Rakowski W, Anderson L. Self-management of chronic disease by older adults: A review and questions for research. *J Aging Health.* 1991;3:3-27. Rec #: 904

Clark NM, Evans D, Zimmerman BJ, Levison MJ, Mellins RB . Patient and family management of asthma: theory-based techniques for the clinician. *J Asthma.* 1994;31(6):427-35. Rec #: 764

Clement S . Diabetes self-management education. *Diabetes Care.* 1995;18(8):1204-14. Rec #: 769

Cox DJ, Gonder-Frederick L. Major developments in behavioral diabetes research. *Journal of Consulting and Clinical Psychology.* 1992;60(4):628-638. Rec #: 2441

Dubbert PM, Rappaport NB, Martin JE. Exercise in cardiovascular disease. *Behavior Modification.* 1987;11:329-347. Rec #: 2643

Dunn S M . Rethinking the models and modes of diabetes education. *Patient Educ Couns.* 1990;16(3):281-6. Rec #: 778

Epstein LH, Cluss PA. A Behavioral Medicine perspective on adherence to long-term medical regimens. *Journal of Consulting and Clinical Psychology.* 1988;6:77-87. Rec #: 2238

Fawzy F I, Fawzy N W, Arndt L A, Pasnau R O . Critical review of psychosocial interventions in cancer care. *Arch Gen Psychiatry.* 1995;52(2):100-13. Rec #: 786

Freemantle N, Harvey EL, Wolf F, et al. Printed educational materials to improve the behavior of health care professionals and patient outcomes. In: *Cochrane Database of Systematic Reviews, Issue 3,* 1998. Rec #: 2618

Giloth B E . Promoting patient involvement: educational, organizational, and environmental strategies. *Patient Educ Couns.* 1990;15(1):29-38. Rec #: 796

Glanz K. Patient and public education for cholesterol reduction: A review of strategies and issues. *Patient Education and Counseling.* 1988;12:235-257. Rec #: 2644

Glasgow R E, Toobert D J, Hampson S E, Wilson W. Behavioral research on diabetes at the Oregon Research Institute. *Ann Behav Med.* 1995;17:32-40. Rec #: 905

Glasgow RE, Osteen VL. Evaluating diabetes education: Are we measuring the most important outcome? *Diabetes Care.* 1992;15:1423-1432. Rec #: 2177

Goodall T A, Halford W K . Self-management of diabetes mellitus: A critical review [published erratum appears in Health Psychol 1992;11(1):77]. *Health Psychol.* 1991;10(1):1-8. Rec #: 802

Griffin S, Kinmonth AL. Diabetes care: the effectiveness of systems for routine surveillance for people with diabetes (Cochrane Review). In: *The Cochrane Library, Issue 4,* 1998. Oxford: Update Software. Rec #: 2620

Hackett TP. The use of groups in the rehabilitation of the postcoronary patient. *Adv Cardiol.* 1978;24:127-135. Rec #: 2411

Haynes RB, McKibbon KA, Kanani R, et al. Interventions to assist patients to follow prescriptions for medications (Cochrane Review). In: *The Cochrane Library, Issue 4,* 1998. Oxford: Update Software. Rec #: 2621

Table 1. Review Articles

Hill D R, Kelleher K, Shumaker S A . Psychosocial interventions in adult patients with coronary heart disease and cancer. A literature review. *Gen Hosp Psychiatry.* 1992;14(6 Suppl):28S-42S. Rec #: 811

Hirano P C, Laurent D D, Lorig K . Arthritis patient education studies, 1987-1991: a review of the literature [see comments]. *Patient Educ Couns.* 1994;24(1):9-54. Rec #: 813

Jacob RG, Wing R, Shapiro AP. The behavioral treatment of hypertension: long-term effects. *Behav Therapy.* 1987;18:325-352. Rec #: 2471

Jacobson AM, Leibovich JB. Psychological issues in diabetes mellitus. *Psychosomatic Illness Review.* 1984;25:7-13. Rec #: 2255

Johnston DW. Behavioral treatment in the reduction of coronary risk factors Type A behavior and blood pressure. *Br J Clin Psychol.* 1982;21:281-294. Rec #: 2364

Johnston DW. Stress managements in the treatment of mild primary hypertension. *Hypertension.* 1991;17(Suppl 3):63-68. Rec #: 2470

Kaplan RM, Davis WK. Evaluating costs and benefits of outpatient diabetes education and nutrition counseling. *Diabetes Care.* 1986;9:81-86. Rec #: 2379

Kaplan S H, Greenfield S, Ware J E. Assessing the effects of physician-patient interactions on the outcomes of chronic disease [published erratum appears in Med Care 1989 Jul;27(7):679]. *Med Care.* 1989;27(3 Suppl):S110-27. Rec #: 820

Keefe F J, Dunsmore J, Burnett R . Behavioral and cognitive-behavioral approaches to chronic pain: recent advances and future directions. *J Consult Clin Psychol.* 1992;60(4):528-36. Rec #: 822

Keefe FJ, Gil KM, Rose SC. Behavioral approaches in the multidisciplinary management of chronic pain: Programs and issues. *Clinical Psychology Review.* 1986;6:87-113. Rec #: 2292

Keefe FJ, Williams DA. New Directions in pain assessment and treatment. *Clinical Psychology Review.* 1989;9:549-568. Rec #: 2293

Kemper D W, Lorig K, Mettler M . The effectiveness of medical self-care interventions: a focus on self-initiated responses to symptoms. *Patient Educ Couns.* 1993;21(1-2):29-39. Rec #: 823

Linden W, Chambers L. Clinical effectiveness of non-drug treatment for hypertension: A meta-analysis. *Ann Behav Med.* 1994;16:35-45. Rec #: 910

Lorig K. Self-management of chronic illness: A model for the future. *Generations.* 1993:11-14. Rec #: 911

Lorig K, Holman H . Arthritis self-management studies: a twelve-year review. *Health Educ Q.* 1993;20(1):17-28. Rec #: 831

Lorig K, Laurin J . Some notions about assumptions underlying health education. *Health Educ Q.* 1985;12(3):231-43. Rec #: 834

Mazzuca S A . Does patient education in chronic disease have therapeutic value? *J Chronic Dis.* 1982;35(7):521-9. Rec #: 843

Mazzuca S A . Education and behavioral and social research in rheumatology. *Curr Opin Rheumatol.* 1994;6(2):147-52. Rec #: 844

Meyer T J, Mark M M . Effects of psychosocial interventions with adult cancer patients: a meta-analysis of randomized experiments [see comments]. *Health Psychol.* 1995;14(2):101-8. Rec #: 848

Mullen P D, Laville E A, Biddle A K, Lorig K . Efficacy of psychoeducational interventions on pain, depression, and disability in people with arthritis: a meta-analysis. *J Rheumatol.* 1987;14 Suppl 15:33-9. Rec #: 850

Mullen PD, Green LW, Persinger GS. Clinical trials of patient education for chronic conditions: a comparative meta-analysis of intervention types. *Prev Med.* 1985;14:753-781. Rec #: 2350

Table 1. Review Articles

Mumford E, Schlesinger H J, Glass G V . The effect of psychological intervention on recovery from surgery and heart attacks: an analysis of the literature. *Am J Public Health.* 1982;72(2):141-51. Rec #: 852

Norris SL, Engelgau MM, Narayan KMV. Effectiveness of self-management training in Type 2 Diabetes. *Diabetes Care*. 2001;24:561-587.

Nunes E V, Frank K A, Kornfeld D S . Psychologic treatment for the type A behavior pattern and for coronary heart disease: a meta-analysis of the literature. *Psychosom Med.* 1987;49(2):159-73. Rec #: 854

O'Connor GT, Collins R, Burning JE et al. Rehabilitation with exercise after myocardial infarction. *Circulation.* 1989;80(2):234-244. Rec #: 2692

Padgett D, Mumford E, Hynes M, Carter R . Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *J Clin Epidemiol.* 1988;41(10):1007-30. Rec #: 857

Razin A M . Psychosocial intervention in coronary artery disease: a review. *Psychosom Med.* 1982;44(4):363-87. Rec #: 864

Rosenstock IM. Understanding and enhancing patient compliance with diabetic regimens. *Diabetes Care.* 1985;8:610-616. Rec #: 2268

Rosenstock J, Raskin P. Diabetes and its complications: Blood glucose control vs. genetic susceptibility. *Diabetes/Metabolism Reviews.* 1988;4:417-435. Rec #: 2269

Schlundt DG, McDonel EC, Langford HG. Compliance in dietary management of hypertension. *Comprehensive Therapy.* 1985;11:59-66. Rec #: 2645

Sobel D S . Rethinking medicine: improving health outcomes with cost-effective psychosocial interventions. *Psychosom Med.* 1995;57(3):234-44. Rec #: 876

Spiegel D . Health caring. Psychosocial support for patients with cancer. *Cancer.* 1994;74(4 Suppl):1453-7. Rec #: 878

Strecher V J, DeVellis B M, Becker M H, Rosenstock I M . The role of self-efficacy in achieving health behavior change. *Health Educ Q.* 1986;13(1):73-92. Rec #: 882

Sunin RM. Intervention with Type A behaviors. *J Consult Clin Psychol.* 1982;50:933-949. Rec #: 2365

Tattersall RB, McCulloch DK, Aveline M. Group therapy in the treatment of diabetes. *Diabetes Care.* 1985;8:180-188. Rec #: 2196

Tobin D L, Reynolds R V C, Holroyd K A, Creer T L. Self-management and social learning theory. In: Holroyd KA, Creer TL. (Eds.) *Self-Management of Chronic Disease: Handbook of Clinical Interventions and Research*. Orlando, FL: Academic Press, 1986. Rec #: 914

Toobert DJ and Glasgow RE. Assessing diabetes self-management: The summary of diabetes self-care activities questionnaire. Berkshire, England: Hardwood Academic. 1994. Rec #: 2446

Turk D, Meichenbaum D. A Cognitive-behavioral approach to pain management. In: Wall P, Melzack R. *Textbook of Paid* . London: Churchill Livingstone, 1994. pgs. 1337. Rec #: 2085

Vickery DM. Medical self-care: a review of the concept and program models. *Am J Health Promotion.* 1986;Summer:23-28. Rec #: 2301

Vijan S Stevens DL Herman et al. Screening, prevention, counseling, and treatment for the complications of type II diabetes mellitus. Putting evidence into practice. *Journal of General Internal Medicine.* 1997;12(9):567. Rec #: 2613

Wagner E H, Austin B T, Von Korff M . Organizing care for patients with chronic illness. *Milbank Q.* 1996;74(4):511-44. Rec #: 894

Watts FN. Behavioral aspects of the management of diabetes mellitus: Education, self-care and metabolic control. *Behavior Research and Therapy.* 1980;18:171-180. Rec #: 2278

Table 1. Review Articles

Wing RR. Behavioral strategies for weight reduction in obese Type II diabetic patients. *Diabetes Care.* 1989;12:139-144. Rec #: 2641

Wing RR, Epstein LH, Nowalk MP, Lamparski D. Behavioral self-regulation in the treatment of patients with diabetes mellitus. *Psychological Bulletin.* 1986;99:78-89. Rec #: 2282

Health Care Quality Improvement Projects (HCQIP)

Each U.S. state and territory is associated with a Medicare Peer Review Organization (PRO) that conducts various research projects. The Centers for Medicare & Medicaid Services (CMS) maintains a database with a narrative description of each research project, called a Narrative Project Document (NPD). An NPD includes the aims, background, quality indicators, collaborators, sampling methods, interventions, measurement, and results of a project. Our search of the NPD database for studies on chronic disease self-management found none.

Experts

We contacted several experts in the field and asked for any studies which were in press or undergoing review or that we had missed in our published literature.

Other Ongoing Reviews of Chronic Disease Self-management

During our review process we became aware of another group in Boston reviewing the evidence on chronic disease self-management. While their focus was somewhat different than ours, both groups were reviewing evidence on some illnesses in common. The two groups therefore agreed to exchange reference lists (but no analytic strategies or results). The list of studies included by the other group was provided by Daniel Solomon, MD.

EVALUATION OF POTENTIAL EVIDENCE

We reviewed the articles retrieved from the literature sources against exclusion criteria to determine whether to include them in the evidence synthesis. A one-page screening review form that contains a series of yes/no questions was created for this purpose (Figure 2). Two physicians, each trained in the critical analysis of scientific literature, independently reviewed each study, abstracted data, and resolved disagreements by consensus. Dr. Shekelle resolved any disagreements that remained unresolved after discussions between the reviewers. Project staff entered data from the checklists into an electronic database that was used to track all studies through the screening process.

While we were searching primarily for data relevant to the Medicare population, we included studies that contained data on populations under age 65 to avoid loss of potentially useful data. To be accepted, a study had to be a controlled clinical trial. We further classified controlled clinical trials as randomized or not, based on the following definitions:

Randomized controlled trial (RCT). A trial in which the participants (or other units) are definitely assigned prospectively to one of two (or more) alternative forms of health care, using a process of random allocation (e.g., random number generation, coin flips).

Controlled clinical trial (CCT). A trial in which participants (or other units) are either (a) definitely assigned prospectively to one of two (or more) alternative forms of health care using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier), or (b) possibly assigned prospectively to one of two (or more) alternative forms of health care using a process of random or quasi-random allocation.

Figure 2. Screening Form

1. Article ID:_____

2. First Author:_____
(Last name of first author)

3. Reviewer:_____

4. Subject of article: **Circle one**
   - Chronic disease self-management 1
   - Other ..... 9 **(STOP)**

   If other, then STOP

5. Do interventions studied satisfy OUR definition of chronic disease self-management? **Check all that apply**
   - Studies a **systematic** intervention ..... ☐
   - …targeted towards **patients** ..... ☐
   - …with **chronic disease** ..... ☐
   - …to help them to **actively participate** ..... ☐
   - …in the following activities: ..... ☐
     - **self-monitoring** (of symptoms or of illness on quality of life), **OR**
     - **decision-making** (managing disease or its impacts based on self-monitoring)

   If ANY are unchecked, then STOP

6. Study design: **Circle one**
   - Descriptive (editorial etc. Do not pull) ..... 0 **(STOP)**
   - Review/meta-analysis (pull article) ..... 1 **(STOP)**
   - Randomized Clinical Trial 2
   - Controlled Clinical Trial 3
   - Controlled Before and After 4
   - Interrupted Time Series 5
   - Simple Pre-Post 6
   - Cohort 7
   - Other 8
   - Unsure 9

   If descriptive or review article, then STOP

7. Conditions studied: (**Check all that apply**):
   - ☐ Heart disease
   - ☐ Heart failure
   - ☐ Angina pectoris
   - ☐ Other heart conditions
   - ☐ Back disorders
   - ☐ Osteoarthritis
   - ☐ Rheumatoid arthritis
   - ☐ Other (sp:_____)
   - ☐ Other (sp:_____)
   - ☐ Emphysema
   - ☐ Asthma
   - ☐ COPD
   - ☐ Hypertension
   - ☐ Diabetes
   - ☐ Other (sp:_____)
   - ☐ Unsure

8. Ages of study participants: **Circle one**
   - Excludes over 65 1
   - Includes over 65 ..... 2 **(Answer #9)**
   - Unsure 9

9. If study **includes** persons 65 and older, are the results reported separately for this group? **Circle one**
   - Yes 1
   - No 2
   - Not applicable 8
   - Unsure 9

Notes:

EXTRACTION OF STUDY-LEVEL VARIABLES AND RESULTS

Using a specialized Quality Review Form (QRF - see Figure 3) we abstracted data from the articles that passed our screening criteria. The form contains questions about the study design; the number and characteristics of the patients; the setting, location, and target of the intervention; the intensity of the intervention; the types of outcome measures and the time from intervention until outcome measurement. We selected the variables for abstraction with input from the project's technical experts. Two physicians, working independently, extracted data in duplicate and resolved disagreements by consensus. A senior physician resolved any disagreements not resolved by consensus.

To evaluate the quality of the study, we collected information on the study design (with the hierarchy of internal validity being RCT, CCT, CBA, and ITS), withdrawal/dropout rate, agreement between the unit of randomization and the unit of analysis, blinding and concealment of allocation.[25]

Figure 3. Quality Review Form

Article ID: _____ Reviewer:_____

First Author: _____
(Last Name Only)

Study Number: _____of_____ Date of Publication:_____
(Enter '1of 1' if only one)

Description (if more than one study):_____

Study Quality

1. Design: (circle one)
   - RCT 1
   - CCT 2

   If not RCT or CCT, then STOP.

2. Does the study present data on people age 50 and up? (circle one)
   - Yes.....1
   - No 2

   If not, reject --STOP.

3. Is the study described as randomized? (circle one)
   - Yes.....1
   - No 2

4. If the study was randomized, was the method of randomization appropriate? (circle one)
   - Yes.....1
   - No 2
   - Method not described.....8
   - Not applicable (not randomized).....9

5. Is the study described as: (circle one)
   - Double blind 1
   - Single blind, patient 2
   - Single blind, outcome assessment 3
   - Open 4
   - Blinding not described 8

6. If reported, was the method of double blinding appropriate? (circle one)
   - Yes.....1
   - No 2
   - Double blinding not described 8
   - Not applicable (not double blinded).....9

7. If study was randomized, did the method of randomization provide for concealment of allocation? (circle one)
   - Yes.....1
   - No 2
   - Concealment not described 8
   - Not applicable (not randomized).....9

8. Are numbers and reasons for withdrawals and dropouts described? (circle one)
   - Yes.....1
   - No 2

9. What is the geographic setting of the study? (circle one)
   - Rural 1
   - Urban/Suburban.....2
   - Mixed.....4
   - Other (specify:_____) 5
   - Not specified.....8

10. What is the setting of study? (circle one)
    - Academic 1
    - Non-academic 2
    - Both academic and non-academic.....3
    - Not specified.....8

11. In what country was the study conducted? (circle one)
    - US 1
    - Great Britain 2
    - France 3
    - Germany 4
    - Other (specify:_____).....5
    - Not specified.....8

Figure 3. Quality Review Forms (con't)

12. What is the refusal rate?

    ___ ___ %

    (Enter NR if not reported)

13. Which best describes the reimbursement system in which the study occurred: (check all that apply)

    - FFS ❑
    - HMO ❑
    - MCO (not HMO) ❑
    - Mixed ❑
    - Other (specify:_____) ❑
    - Not sure ❑

14. Are data stratified by any of these groups or does a group make up ≥ $^{2}/_{3}$ of the subjects? (check all that apply)

    - 85 and older ❑
    - African-American ❑
    - Hispanic ❑
    - Other minority ❑
    - Low income ❑
    - Nursing home ❑
    - Veterans ❑
    - Other (specify:_____) ❑
    - None of the above ❑

15. Comorbid conditions (check all that apply)

    - Heart disease (not hypertension) ❑
    - Hypertension ❑
    - Kidney (renal) disease ❑
    - Chronic respiratory disease ❑
    - PVD ❑
    - Neuropathy ❑
    - Obesity ❑
    - DM ❑
    - Arthritis ❑
    - CHF ❑
    - Tobacco Abuse ❑
    - Angina ❑
    - Other (specify:_____) ❑
    - None specified ❑

DIABETES STUDIES ONLY:

16. Type of diabetes: (circle one)

    - Type I DM (IDDM) 1
    - Type II DM (NIDDM) 2
    - Both types 3
    - Not specified 8

17. Which baseline diagnostic criteria were used? (check all that apply)

    - Fasting blood sugar ❑
    - Urine glucose ❑
    - HgbA1c ❑
    - Other (specify:_____) ❑
    - Diagnostic criteria not specified ❑

OA/RA STUDIES ONLY:

18. Type of disease: (circle one)

    - RA only 1
    - OA only 2
    - OA and RA 3
    - Arthritis NOS 4

19. Which baseline diagnostic criteria were used? (check all that apply)

    - X-ray ❑
    - Physical Exam ❑
    - MD diagnosis w/o other detail ❑
    - Other (specify:_____) ❑
    - Diagnostic criteria not specified ❑

MI STUDIES ONLY:

20. Type of disease: (check all that apply)

    - Uncomplicated ❑
    - Complicated ❑
    - First Occurrence ❑
    - Recurrence ❑
    - Angina w/o infarction ❑
    - Angina w/ infarction ❑
    - Unsure/ unspecified ❑

21. Which baseline diagnostic criteria were used? (check all that apply)

    - CPK-MB elevation ❑
    - Cardiac troponins ❑
    - ECG ❑
    - Diagnostic criteria not specified ❑
    - Other (specify:_____) ❑

Figure 3. Quality Review Forms (con't)

If study has a control group, then enter data for that group here. Otherwise, enter data for each group in order of first mention. Complete one page for each arm

Arm ____ of ____ Description:_____

Use these abbreviations for interval:

MI	minute	WK	week	ND	not described
HR	hour	MO	month	NA	not applicable
DY	day	YR	year		

22. Intervention:

	Intervention component	Target	Content	Delivery by/during	Provider type	Setting	Frequency per interval		Duration of session/ units		Total # of sessions	Total duration / units		Grouped With
1.														
2.														
3.														
4.														
5.														
6.														
7.														
8.														
9.														
10.														
11.														
12.														
13.														
14.														
15.														
16.														

23. What was the sample size in this intervention arm?

___ ___ ___ , ___ ___ ___ ___ ___ ___ , ___ ___ ___
Entering Completing

(Enter 999,999 if not reported.)

IF "usual care" then SKIP to next page

24. Was there a protocol for the intervention? (circle one)
- Yes.....1
- No.....2
- Protocol not mentioned.....8

25. Was the intervention tailored to the individual? (circle one)
- Yes.....1
- No.....2
- Qualifications not described.....8

26. What was the length of the intervention period?

_____ _____
Number Units

Enter MI, HR, DY, WK, MO, YR as defined above

27. Were the intervention providers' qualifications appropriate? (circle one)
- Yes.....1
- No.....2
- Qualifications not described.....8

28. Were the providers homogeneous? (circle one)
- Yes.....1
- No.....2
- Therapists not described.....8

Figure 3. Quality Review Forms (con't)

Outcomes, Evaluation, and Statistics

29. Type of outcomes measured:

Enter the code for each outcome measured. Circle at least one of the letters "P", "A", and "L" for each outcome measured. If rating method is not described, circle ONLY "ND".	Patient, assessor, or laboratory rated? (ND=not described)
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND
	P **A** **L** ND

30. When, relative to the start of the intervention, were outcomes measured?

Enter the number of weeks in the appropriate box. Enter '999' if not applicable.

	Number	**Unit**
1st follow-up		
2nd follow-up		
3rd follow-up		
4th follow-up		
5th follow-up		

use the following abbreviations for units:

MI	minute
HR	hour
DY	day
WK	week
MO	month
YR	year

31. What was the unit of allocation? (circle one)
    - Patient 1
    - Provider.....3
    - Organization (practice, hospital, HMO, community).....4
    - Other (specify:_____) 6
    - Not reported 8

32. What was the unit of analysis? (circle one)
    - Patient 1
    - Provider.....3
    - Organization (practice, hospital, HMO, community).....4
    - Other (specify:_____) 6
    - Not reported 8

33. If the unit of allocation is not the same as the unit of analysis, was any statistical correction made for clustering? (circle one)
    - Yes 1
    - No 2
    - Not sure.....8
    - Not Applicable 9

34. Was any cost information provided? (circle one)
    - Yes 1
    - No 2

Figure 3. Quality Review Forms (con't)

Hypertension Only Studies

Article ID: _____ Reviewer:_____
First Author:_____
Description:_____

35. Types of hypertension (circle one)
- Essential 1
- Secondary 2
- Both 3
- Not specified 8
- Not applicable 9

36. Types of hypertension (circle one)
- Systolic 1
- Diastolic 2
- Both 3
- Not specified 8
- Not applicable 9

37. Types of hypertension (circle one)
- Treated 1
- Untreated 2
- Both 3
- Not specified 8
- Not applicable 9

38. Which baseline diagnostic criteria were used? (check all that apply)
- One blood pressure recording ..... ❑
- More than 1 recording ..... ❑
- MD diagnosis ..... ❑
- Other (specify:_____) ... ❑
- Diagnostic criteria not specified ..... ❑

39. Medication Treatment? (circle one)
- Yes 1
- No 2
- Other: (specify:_____) ... 3
- Not specified 8
- Not applicable 9

Figure 3. Quality Review Forms (con't)

Code Sheet

Intervention components

1. Control
2. Usual Care
3. Advocacy training (how to ask MDs)
4. ASMP (Arthritis self-management)
5. Clinical reviews w/ patient
6. Cognitive-behavioral (including relaxation training)
7. Consultation with specialists
8. Contracts
9. Counseling/Therapy
10. Dietary monitoring
11. Education
12. Feedback
13. Financial incentives
14. Mass media
15. Nontraditional therapies (massage, acupuncture, biofeedback, etc.)
16. Practice methods
17. Psychological assessment/care
18. Emotional support
19. Reminders/reinforcement
20. Material incentive
21. Referrals
22. Unstructured group time
23. Exercise program
24. Competition between groups
25. Exercise diary
26. Follow up
27. Social/peer support
28. Cholesterol lowering medication
29. Placebo medication
30. Practice self care skills
31. Goal setting
32. Exercise testing
33. Exercise monitoring
34. Patient directed discussion group
35. Compensation for participation
36. Practice diagnostic skills
37. Blood pressure monitoring
38. Self monitoring
39. Medication therapy
40. Blood pressure lowering medication
99. Component not specified

Targets, provider types

1. Patients
2. Physicians
3. Psychologists
4. Psychiatrists
5. Nurses
6. Nurse practitioners
7. Other/non-specified medical professionals
8. Educators
9. Nutritional Expert
10. Office Staff
11. Non-medical personnel not staff
12. Lay leaders
13. Lay (affected) leaders/role models
14. Family members
15. Research assistants
16. Qualified researchers
17. Researchers, qualifications not specified
18. Physical/Occupational Therapists
19. Health care organizations (e.g., HMOs)
20. Hospitals
21. Clinics
22. Practices
23. Other organizations, not specified
24. Group facilitator
25. Podiatrist
26. Pharmacist
27. Exercise leader
28. Medical student
29. Exercise therapist
30. Social worker
31. Physician assistant
32. Therapist/counselor
33. _
34. _
35. Psychologists and nurses

Figure 3. Quality Review Forms (con't)

Code Sheet

Specific Content

1. Behavioral assessment/strategies
2. Diet
3. Disease information
4. Exercise
5. Foot care
6. Medication information/compliance
7. Pain coping skills
8. Physical activity
9. Prevention NOS
10. Smoking cessation
11. Stress management
12. Weight management
13. Sleep/fatigue management
14. Symptom management
15. Use of community resources
16. Communication skills
17. Problem solving/decision making
18. Goal setting
19. Empowerment
20. Communicating with professionals
21. Treatment information
22. Adherence/compliance
23. Self-help
24. BG(Blood Glucose) machine use
25. Sexual activity/dysfunction
26. Complementary therapy
27. Cognitive assessments/strategies
28. Self-monitor
29. Blood glucose monitor
30. Joint preservation
31. Relaxation methods
32. Emotional symptoms
33. Urine monitor
34. Metabolic control
35. Educational methods
36. Rehabilitation
37. Blood pressure
38. Psychotherapy
39. Exercise capacity
40. Pain
41. CPR
42. Cardiac function
43. Work
44. Psychosocial issues
45. Medication administration
46. Physical exam
47. Alcohol
48. Peer support
49. Symptoms NOS
50. Depression
99. Content not specified

Content Delivered By/During

1. Group meeting
2. Office visit
3.
4. Hospitalization
5. Home visit
6. Telephone
7. Mail (postcards, letters)
8. Detailed reading materials mailed (pamphlets, newsletters)
9. Detailed reading materials (hand-outs)
10. Instructional manuals
11. Computer program
12. Email/Internet
13. Video/Audio tapes
14. Other mechanisms
15. One on one NOS
16. Protocols
17. Detailed reading materials NOS
18. Self-delivery
19. Prescription
99. Mechanism not specified

Settings

1. Hospital
2. Home
3. In office
4.
5. Other setting specified (write in)
6. Nursing home
7. Day center
8. Community Center
99. Setting not specified

Frequency Per Interval

98. Variable frequency

Figure 3. Quality Review Forms (con't)

Code Sheet

Outcomes

DIABETES

1. Diabetic complications
2. Foot care activity
3. Foot lesions
4. FSBG
5. $HgbA_{1c}$
6. Hypoglycemic episodes
7. Self monitoring frequency (BG)
8. Diabetic symptoms
9. Postpandrial blood glucose
10. C-peptide
11. Urine glucose
12. Self-monitoring accuracy
13. Plasma insulin
14. Creatinine
15. Self-monitoring frequency(UG)

OA

30. Pain measurement
31. Physical performance
32. Mobility
33. Stiffness

MI

60. "Rose" questionnaire
61. Cholesterol
62. Occurrence/Reoccurrence of MI
63. Sexual activity (same as 112)
64. Tobacco use
65. Hypertension
66. Angina
67. Arrhythmia
68. CABG
69. Ischemic heart disease
70. CHF
71. Cardiac symptoms
72. Angioplasty (PTCA)
73. Chest pain
74. ECG
75. Exercise tolerant test (ETT)/Treadmill

OTHER/COMMON

90. MD visits
91. Nurse visits
92. Behavioral measures
93. Blood pressure
94. Coping strategies
95. Depression assessment
96. Dietary measures
97. Disability, physical
98. Disease duration
99. Emotional well-being
100. Exercise frequency
101. Health service utilization NOS
102. Hospitalization
103. Hospitalizations (Days)
104. Interpersonal support
105. Mortality
106. Patient knowledge
107. Patient Satisfaction
108. Provider Satisfaction
109. Psychological measures
110. Quality of life scales
111. Self-efficacy (helplessness)
112. Social assessment
113. Weight control
114. Self rated health
115. ER visits
116. Functional status
117. Medication compliance
118. Medication use
119. Work activity
120. Sexual activity (same as 63)
121. Physical activity
122. BMI (Body Mass Index)
123. Self care
124. Physician-patient interactions
125. Cardiac procedures
126. Compliance/adherence
127. Marital Adjustment
128. Aerobic capacity (VO2Max)
129. Anaerobic threshold
130. Skin fold thickness
131. Problem solving
132. Anxiety
133. Exercise capacity (METS)
134. Alcohol use
135. Heart rate
136. Symptoms
137. Catecholamines
138. Urinary sodium
139. Physiologic measures
140. Renin
141. Cognitive measures
142. BUN (plasma urea)
999. Not specified

STATISTICAL METHODS

In the analysis, we sought to answer the questions specified by CMS that can be found at the beginning of the Methods Section.

Our summary of the evidence is both qualitative and quantitative. We first assessed the distribution of studies based on the classification of interventions as specified in our data abstraction form (Figure 3). For many of the fourteen specific questions listed above, the evidence was too sparse and/or heterogeneous to support statistical pooling. In these cases, our summary of evidence is qualitative.

To help answer Question 2 posed by CMS, we proposed five overall hypotheses that encompassed the questions concerning intervention components. These hypotheses were listed in the introduction. We denote these as the "original" hypotheses to distinguish them from post-hoc hypotheses we tested subsequently. We recoded each intervention arm in each study into "yes" (met hypothesis) or "no" (did not meet hypothesis), and conducted analyses to test these hypotheses as described below.

Meta-Analysis

We conducted separate meta-analyses for each of the four conditions: diabetes, osteoarthritis, post-myocardial infarction care, and hypertension. Though separate, these analyses were sufficiently similar that we will discuss our general analytic approach, inserting comments about specific outcomes or conditions as needed.

We first identified the most commonly reported clinically relevant outcome or outcomes for each condition. These outcomes were:

- for diabetes
  - fasting blood glucose
  - hemoglobin A1c
  - weight
- osteoarthritis
  - pain
  - functioning
- post-myocardial infarction care
  - mortality
  - return to work
- hypertension
  - systolic blood pressure
  - diastolic blood pressure

We considered only studies that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group and that provided outcome data.

The majority of our outcomes were continuous. For these outcomes we extracted data to estimate effect sizes. The effect size for the study's comparison between a particular intervention arm and usual care or control arm is the difference between the intervention group and usual care or control group divided by its standard deviation, and is therefore a unitless

measure convenient for comparing studies measuring outcomes in the same domain but using different measures. For the two dichotomous outcomes (mortality and return to work for post-myocardial infarction care), we estimated risk ratios. We will discuss each of these general types of outcomes in turn.

Because follow-up times across studies can lead to clinical heterogeneity, we excluded from analysis any studies whose data were not collected within a specified follow-up interval. These intervals were chosen based on clinical knowledge. For diabetes, studies that had a follow-up time between three and twelve months were included. Four studies were excluded because their follow-up time fell outside this interval. For osteoarthritis, all studies retrieved included a follow-up time between four and six months. One study had multiple follow-up times between four and six months, and we included the measurement that was closest to six months. For post-myocardial infarction care, studies that had a follow-up time between six and twelve months were included, and no studies were excluded due to follow-up time. For hypertension, all studies were included; a follow-up time between two and six months was used. Four studies had multiple follow-up times but had only one data point in between two and six months, and we included this measurement in our analysis.

Some studies had more than one intervention arm of interest. For these "multi-arm" studies, we estimated one effect size or one risk ratio (depending on the outcome) for each comparison between an intervention arm and the control or usual care group. The possibility that a single study might contribute multiple treatment effects to a meta-analysis was addressed via a sensitivity analysis discussed below.

Data extraction and basic calculations were performed in the statistical package SAS[26] and the spreadsheet package Excel.[27] The majority of the modeling was performed in the

statistical package Stata,[28] with some special modeling implemented in StatXact[29] for the mortality outcome, and sensitivity analyses conducted in statistical software package SAS[26] as described below.

Continuous Effect Sizes

For each study, we estimated an effect size for each comparison that was considered relevant, that is for each intervention arm of interest as compared with the usual care or control arm. The follow-up mean and standard deviation of each outcome for each relevant arm were extracted if available. If a study did not report a follow-up mean, or a follow-up mean could not be calculated from the given data, the study was excluded from the meta-analysis.

For studies that did not report a standard deviation or for which a standard deviation could not be calculated from the given data, we imputed the standard deviation by using those studies and arms that did report a standard deviation and weighting all arms equally, or we assumed that the standard deviation was 0.25 of the theoretical range for the specific measure in the study. For example, if a study measured pain on a 0-100 scale, we assumed the standard deviation was 25.

No imputation was required for the diabetes outcomes. For osteoarthritis outcomes, we used the range approach to impute the standard deviations for pain and functioning for five studies. For hypertension outcomes, we used five of the studies to impute the standard deviations for both blood pressure outcomes for the remaining six studies. The post-myocardial infarction care outcomes were dichotomous and required no imputation, as discussed below.

For each comparison of interest, an unbiased estimate[9] of Hedges' g effect size[10] and its standard deviation were calculated. A negative effect size indicates that the intervention is

associated with a decrease in the outcome at follow-up as compared with the control or usual care group. For example, in the osteoarthritis meta-analysis, the outcome was pain, so a negative effect size indicated that the intervention was associated with a decrease in pain at follow-up as compared with the control group.

Risk Ratio Calculations for Dichotomous Outcomes

For the return-to-work outcome for post-myocardial infarction care, we estimated log risk ratios and standard deviations. We conducted the analysis on the logarithmic scale for variance-stabilization reasons.[30] We then back-transformed to the risk ratio scale for interpretability.

A risk ratio greater than one indicates that the risk of the outcome in the intervention arm is larger than that in the control or usual care arm. For example, if the risk ratio is 1.10, then patients in the intervention group are 1.10 times as likely to return to work as those in the control or usual care arm.

One study reported that all patients in a particular arm returned to work. For this study, we performed a continuity correction by adding 0.5 to all cells in the two-by-two table of arm by outcome. This continuity correction is necessary in order for the risk ratio and its standard deviation to be estimated.

Mortality was a rare event and the asymptotic method used for the return-to-work outcome would have required continuity corrections for many studies, not just one as in the return-to-work situation. We were concerned that many corrections would bias our results. Thus, we employed exact calculations to estimate the risk ratios using statistical software package StatXact.[29] This approach uses exact nonparametric inference and, in particular, does not require continuity corrections to be performed for zero cells. For mortality, a risk ratio less

than one indicates that the risk of mortality in the intervention arm is smaller than that in the control or usual care arm.

Analysis

For each condition and outcome except for mortality, we conducted the same analysis. For this analysis, we first calculated a pooled random effects estimate[11] of the treatment effect, a pooled effect size for continuous outcomes, or a pooled log risk ratio for the dichotomous outcome of return to work, as appropriate, across all studies and their associated 95% confidence interval. We then back-transformed to the risk ratio scale for return to work. We used exact calculations to estimate the pooled risk ratio of mortality directly. We assessed the between-study heterogeneity for each outcome using a chi-squared test of heterogeneity p-value.[9]

For each of the original five hypotheses, study arms either meet the criteria (a “yes”) or do not (a “no”), thus no missing values exist. For each hypothesis, a simple stratified analysis would have produced a pooled estimate of the treatment effect for all the “yes” study arms together and a pooled estimate for all the “no” study arms together. To facilitate testing the difference between the two pooled estimates, we constructed these estimates using a meta-regression model in which the only variables in the regression were a constant, and an indicator variable equal to one if the study arm met the hypothesis and zero if the study arm did not. For some outcomes and hypotheses, all study arms were either "yes" or "no". In this case, we could not fit a model, and we labeled those situations as “not estimable (NE)” in our Results tables.

A random effects meta-regression[31] allows a straightforward statistical test of the coefficient for the indicator variable, which is equivalent to testing whether the “yes” pooled treatment effect and the “no” pooled treatment effect are equal, i.e., whether there is evidence

against the hypothesis. In addition, we estimated 95% confidence intervals for each treatment effect ("yes" and "no"). If the confidence interval does not contain the null value of zero (for a continuous outcome) or one (for a risk ratio outcome), the treatment effect is probably statistically significant. For each outcome, we fit five separate regressions, corresponding to the five original hypotheses. We estimated these models in the statistical package Stata[28] using the "metareg" command with the restricted maximum likelihood estimation option.[32]

For the mortality outcome, we used exact calculations to conduct the stratified analyses separately and observed whether the resulting confidence intervals overlapped in order to determine if there was evidence against each hypothesis. For this outcome, we did not allow multiple intervention arms per study to contribute to a single stratified analysis. To eliminate this occurrence, we collapsed the data over multiple intervention arms within a single study within each stratified analysis. By collapsing the data, we mean we aggregated the numbers of patients and deaths across all intervention arms in a single study into a combined single intervention arm.

As an overall test of all the hypotheses, we combined the pain outcomes from osteoarthritis studies, hemoglobin A1c outcomes from diabetes studies, and systolic blood pressure outcomes from hypertension studies into one analysis and fit the five separate regressions as above. These outcomes were chosen because we judged them to be the most clinically relevant continuous outcomes for each condition. We also fit a sixth regression that had a constant and all five indicator variables for the separate hypotheses included. Post-myocardial infarction care studies did not have a continuous outcome, so we could not include it in our overall test of the hypotheses.

Sensitivity Analyses

Within each regression, and especially in the combined analysis, our primary analyses ignored the fact that some studies had multiple intervention arms and thus could contribute more than one treatment effect to the analysis. The correlation between treatment effects within the same study, due to the fact the each intervention arm was compared to the same control or usual care arm, was ignored in this analysis. Among diabetes studies, two studies had two intervention arms each; among osteoarthritis studies, three studies had two intervention arms; and among hypertension studies, four studies had two intervention arms, and two studies had three intervention arms. In post-myocardial infarction care, we collapsed across intervention arms in the same study as done in the primary mortality analysis. For this outcome, two studies had two intervention arms and one study had five intervention arms.

Our sensitivity analyses consisted of refitting the meta-regression models using a two-level random effects model that contains a random effect at the study level, as well as one at the arm level. This hierarchical approach controls for the potential correlation within arms in the same study. We estimated these models in the statistical software package SAS[26] using PROC MIXED.

For the mortality outcome, no sensitivity analysis of the possible effect of multiple intervention arms was needed as we collapsed prior to analysis as described above. None of these sensitivity analyses results differed markedly from that of the primary analysis we present in this report.

Assessment of publication bias

We assessed the possibility of publication bias by evaluating funnel plots of effect sizes or log risk ratios for asymmetry, which results from the non-publication of small, negative studies. Because graphical evaluation can be subjective, we also conducted an adjusted rank correlation test[33] and a regression asymmetry test[34] as formal statistical tests for publication bias. We conducted these tests at the intervention arm level, and also at the study level by choosing only the most statistically significant treatment effect for multi-arm studies as a sensitivity analysis. We conducted all analyses and constructed all graphs using the statistical package Stata.[28]

COST EFFECTIVENESS

To assess the cost-effectiveness of the interventions, we first determined whether the studies included cost data. We chose to summarize these studies qualitatively because of heterogeneity.

EXPERT REVIEW PROCESS AND POST-HOC ANALYSES

The draft evidence report was presented to a group of experts in chronic disease self-management at a meeting convened by the Robert Wood Johnson Foundation and held in Seattle on December 14, 2001. The list of experts attending is present in Appendix A. At this meeting, the draft evidence report, which had been mailed to each panelist several weeks in advance, was presented and discussed. As a result of this discussion several additional hypotheses and analyses were proposed, which we term "post-hoc" hypotheses and analyses since they were generated after seeing the results of the original five hypotheses analyses. These "post-hoc" hypotheses and analyses were:

- Assessing the effectiveness of intervention components as defined by the RE-AIM model of Glasgow.
- Assessing the effectiveness of CDSM programs stratified by severity of illness at baseline.
- Assessing the effectiveness of CDSM program components as classified by the "Essential Elements of Self-management Interventions," which was the result of the group discussion at the Seattle meeting.
- Assessing the effectiveness of CDSM program that assessed and demonstrated improvement in "intermediate" variables according to the following conceptual model:

Intervention →	knowledge, self-efficacy, attitudes	→	dietary measures physical activity behavior	→	hemoglobin A1c pain blood pressure

With regard to the first suggested analysis, components of CDSM were classified in RE-AIM as including:[12]

- one-on-one counseling interventions,
- group sessions,
- interactive computer-mediated interventions,
- telephone calls,
- mail interventions, and
- health system policies.

We coded each of our included articles as having each component present or not, and then conducted meta-analysis and meta-regression analyses for each hypothesis using the method described previously for our original hypotheses. “Health system policies” was particularly difficult to define, so we developed both a “strict” and a “broad” definitions, and tested each.

With regard to stratifying by severity at presentation, we assessed those studies that presented baseline information on blood pressure, hemoglobin A1c, weight, glucose control, pain, and function, and stratified these into two categories: “more severe” and “less severe.” We were not able to stratify the hypertension studies or diabetes studies reporting fasting blood glucose outcomes as the distributions of baseline values in these studies did not support a “threshold” value. We were able to stratify by severity for hemoglobin A1c, weight, pain, and functioning. Effect sizes were then compared between studies of “more severe” and “less severe” patients at baseline.

With regard to the “Essential Elements of Self-management Interventions,” these were defined by the Seattle Expert Panel to be:[13]

1. problem-solving training that encourages patients and providers
    - identify problems
    - identify barriers and supports
    - general solutions
    - form an individually tailored action plan, including:
        - long and short-term goals
        - goals that are measurable and achievable

- monitor and assess progress toward goals, including feedback
- adjust the action plan as needed, reinforcing positive outcomes
    - repeat problem-solving process, enhancing the person's
        - confidence or self-efficacy ("I can do it.")
        - skill mastery ("Here's how.")
        - modeling ("I am not alone.")
        - Social persuasion ("I can be a role model for others.")
        - Ability to re-interpret symptoms ("I know what different symptoms mean.")

2. follow-up
    - maintain contact and continued problem-solving support via one of many available modalities (e.g., telephone, e-mail, mail, etc)
    - identify patients who are not doing well and assist them in modifying their plan and actions to ensure optimal outcomes
    - relate plan to patient's social/ cultural environment
        - teach patients how to connect with resources and support in their own community because the need for these links changes over time
3. tracking and ensuring implementation
    - programs should be linked to the individual's regular source of medical care

        - communication among the patient, the self-management delivery staff, and the patient's usual provider of medical care is likely to improve results
    - programs should monitor their effects on patients' health, satisfaction, quality of life, and the health-system quality measures in order to help make improvements over time and to help decision-makers evaluate the benefits

For our purposes, the studies available were not characterized in detail sufficient to perform an analysis except at the coarsest level of aggregation:

- problem-solving training
- follow-up
- tracking and ensuring implementation

Each of our included studies was characterized as having these features as present or absent, and then we performed meta-analysis and meta-regression analyses for each hypothesis using the method previously described. We ran a meta-regression controlling for each of the three components separately. We then ran a meta-regression controlling for all three components simultaneously and calculated an adjusted effect size for each component.

Lastly, to assess the effectiveness of CDSM programs according to their effect on intermediate variables, we identified those studies that assessed intermediate variables and with the help of Russ Glasgow, MD, we classified these into the previously presented model. We then assessed the effectiveness of the CDSM programs by regressing the effect size of "intermediate 2 variables" (such as dietary measures, physical activity, behavioral measures) on "intermediate 1 variables" (such as self-efficacy, patient knowledge, psychological measures) and regressing the effect size of "outcome variables" (such as hemoglobin A1c, pain, systolic

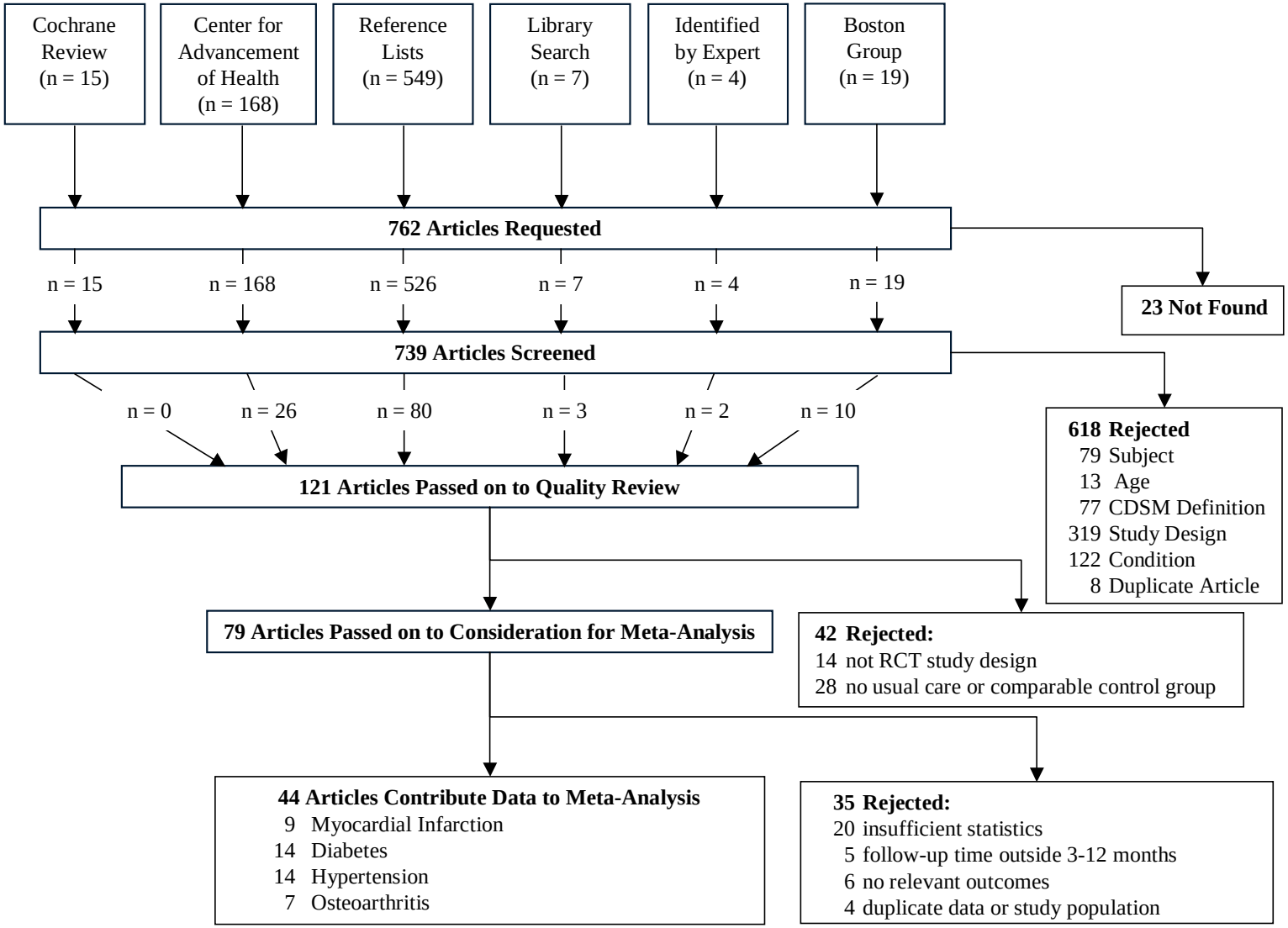
blood pressure) on “intermediate 2 variables.” The conceptual model for these analyses is that studies with interventions that promote improvements in self-efficacy, patient knowledge, and psychosocial measures should be more likely to result in improvements in dietary measures, physical activity, and behavioral measures, which in turn should lead to improvements in outcomes measures such as hemoglobin A1c, pain, and blood pressure. Therefore, studies that measured these “intermediate variables” can be assessed to see if their evidence support this conceptual model.

RESULTS

IDENTIFICATION OF EVIDENCE

Figure 4 describes the flow of evidence from the original sources to final acceptance for our review. The Cochrane Database provided 15 relevant citations. From the Center for Advancement of Health publication, *An Indexed Bibliography on Self-management for People with Chronic Disease,* we ordered 168 articles based on a review of included abstracts. 549 additional articles were ordered upon review of the reference lists from these articles. A library search yielded an additional seven articles and four additional articles not previously noted were obtained from experts. From the Boston group, we received a reference list of 62 articles included in their analysis that were not in our dataset. Of these, however, only nineteen were considered for screening after title review. Articles were rejected at title review because their focus was on conditions not included in our analysis (such as studies of asthma, rheumatoid arthritis, or fibromyalgia), or concerned children or young adults (Figure 5). In total, the above sources yielded 762 articles. We were unable to obtain 23 of these. This left 739 articles for the screening process.

Figure 4. Flow of Evidence



Of the 739 articles screened, 79 did not assess chronic disease self-management. Three hundred nineteen were rejected because they were not randomized controlled trials (RCTs) or controlled clinical trials (CCTs), 13 because they did not satisfy the age criteria (not adults), and 122 did not discuss one the conditions of interest (osteoarthritis, diabetes, hypertension, or post-myocardial infarction care). Another 8 articles were duplicates of articles already on file. Seventy-seven others did not meet our chronic disease self-management definition. This left 121 articles for further review.

SELECTION OF STUDIES FOR THE META-ANALYSIS

Studies that met the inclusion criteria listed above were reviewed in more detail for potential inclusion in the meta-analysis. At the first stage of this review, a study needed to be an RCT and compare a chronic disease self-management program to a control or usual care group. Of the 121 studies accepted for quality review, 79 went on to be considered for meta-analysis because they were randomized controlled trials with a usual care or comparable control group. These studies were then reviewed in more detail regarding their reported outcomes and follow-up times. Based on the distribution of these outcomes and follow-up times, and using our clinical judgment, we accepted into the next stage diabetes studies that reported any of the following outcomes: hemoglobin A1c, weight, and/or fasting blood glucose, with a follow-up time between 3 - 12 months. If there was more than one follow-up time, the time closest to 12 months was selected for inclusion in the final analysis. For osteoarthritis, we accepted studies that reported a pain outcome or a function outcome. For post-myocardial infarction care, we used studies with return to work and mortality outcomes. For hypertension, studies that reported mean systolic and diastolic blood pressure outcomes, with follow-up time of between 8 weeks to

6 months were selected for inclusion. If more than one follow-up time was reported, the time closest to 6 months was selected.

Of the 79 studies considered for meta-analysis, 35 studies were excluded because of insufficient statistics and/or follow-up times, no relevant outcomes, duplicate data (data presented in another included study), or duplicate study populations. From the 19 articles received from the Boston group only two meet the eligibility criteria for our meta-analysis, the remainder being rejected due to not being a controlled trial, not having a usual care or comparable control group, or not having sufficient statistical data for meta-analysis (Figure 5). Therefore, forty-four studies contributed data to the meta-analysis (14 diabetes studies, 7 osteoarthritis studies, 9 post-myocardial infarction care studies, and 14 hypertension studies; see Tables 2-5).

Figure 5. Article Flow of References from Boston Group

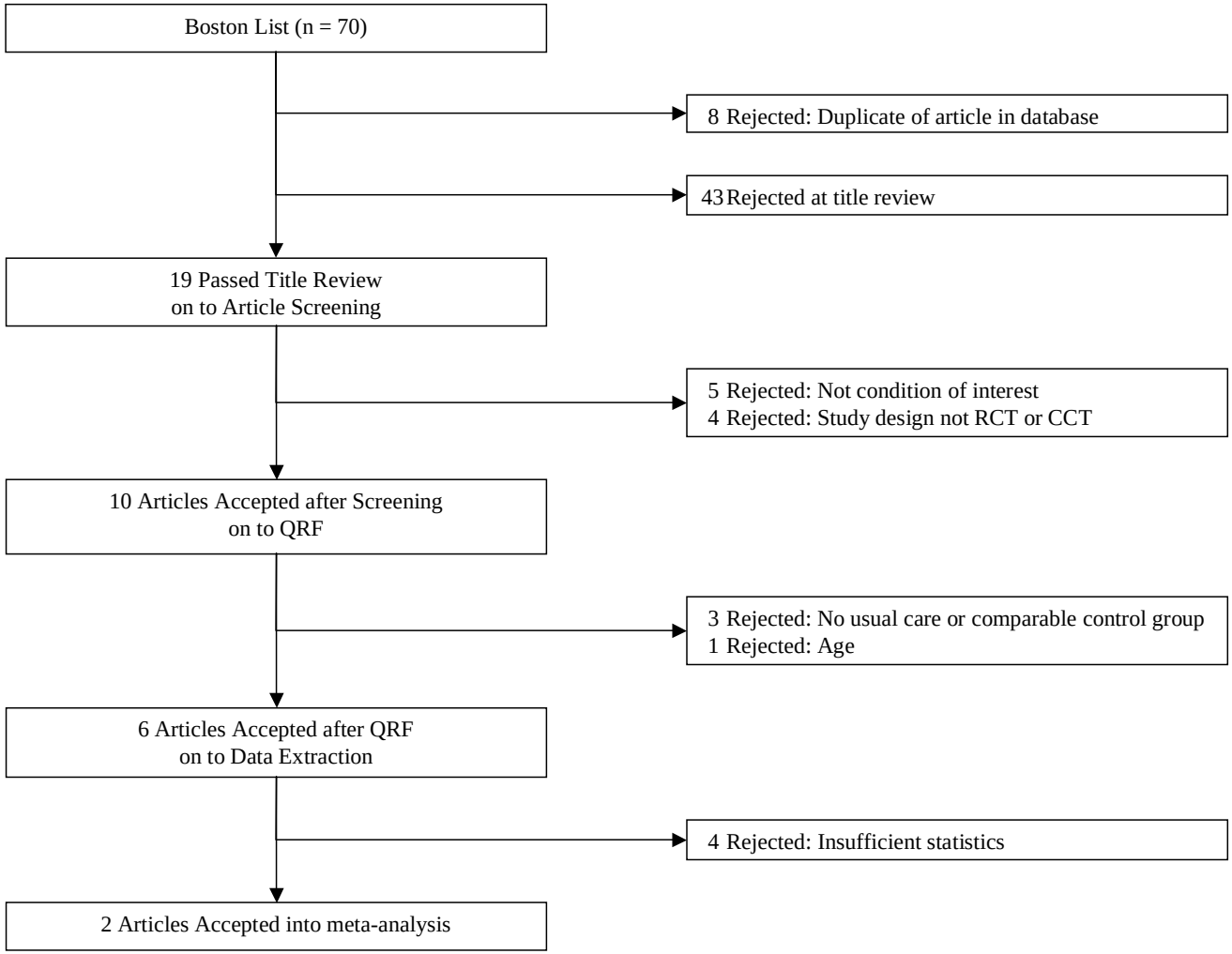


Table 2. Articles Rejected from Meta-analysis

Diabetes Articles	Reason for Exclusion
Integrated care for diabetes: clinical, psychosocial, and economic evaluation. Diabetes Integrated Care Evaluation Team. *BMJ.* 1994;308(6938):1208-1212. Rec #: 2614	no usual care or comparable control group
Allen BT, DeLong ER, Feussner JR. Impact of glucose self-monitoring on non-insulin-treated patients with type II diabetes mellitus. *Diabetes Care.* 1990;13:1044-1050. Rec #: 2201	no usual care or comparable control group
Anderson R M, Funnell M M, Butler P M, Arnold M S, Fitzgerald J T, Feste C C . Patient empowerment. Results of a randomized controlled trial. *Diabetes Care.* 1995;18(7):943-9. Rec #: 747	not RCT
Arseneau D L, Mason A C, Wood O B, Schwab E, Green D . A comparison of learning activity packages and classroom instruction for diet management of patients with non-insulin-dependent diabetes mellitus. *Diabetes Educ.* 1994;20(6):509-14. Rec #: 749	no usual care or comparable control group
Aubert RE Herman WH Waters J et al. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. A randomized, control trial (see comments). *Annals of Internal Medicine.* 1998;129(8):605. Rec #: 2581	no usual care or comparable control group
Bethea DC, Stallings SF, Wolman PG, Ingram RC. Comparison of conventional and videotaped diabetic exchange lists instruction. *Journal of the American Dietetic Association.* 1989;89:405-406. Rec #: 2105	not RCT
Bloomgarden ZT, Karmally W, Metzger J, Borhters M, Nechemias C, Bookman J, et al. Randomized, controlled trial of diabetic education: improved knowledge without improved metabolic status. *Diabetes Care.* 1987;10:263-272. Rec #: 2172	follow-up time not 3-12 months
Boehm S, Schlenk E A, Raleigh E, Ronis D . Behavioral analysis and behavioral strategies to improve self- management of type II diabetes. *Clin Nurs Res.* 1993;2(3):327-44. Rec #: 754	insufficient statistics
Campbell EM Redman S Moffitt PS et al. The relative effectiveness of educational and behavioral instruction programs for patients with NIDDM: a randomized trial. *Diabetes Educator.* 1996;22(4):379. Rec #: 2586	insufficient statistics
de Bont AJ, Baker IA, St Leger AS, Sweetman PM, Wragg KG, Stephens SM, et al. A randomized controlled trial of the effect of low fat diet advice on dietary response in insulin independent diabetic women. *Diabetologia.* 1981;21(6):529. Rec #: 2210	no usual care or comparable control group
Emori KH. The Use of a Programmed Textbook in Diabetic Patient Education. Loma Linda, CA: Loma Linda University; 1964. [Dissertation]. Rec #: 2118	follow-up time not 3-12 months
Glasgow RE/Toobert DJ, Mitchell DL, Donnely JE, Calder D. Nutrition education and social learning interventions for type II diabetes . *Diabetes Care.* 1989;12:150-152. Rec #: 2209	insufficient statistics
Glasgow R E, Toobert D J, Hampson S E . Effects of a brief office-based intervention to facilitate diabetes dietary self-management. *Diabetes Care.* 1996;19(8):835-42. Rec #: 799	insufficient statistics
Glasgow RE, La Chance PA, Toobert DJ, Brown J, Hampson SE, Riddle MC. Long-term effects and costs of brief behavioural dietary intervention for patients with diabetes delivered from the medical office. Patient Educ Couns 1997;32(3):175-84. Rec #: 3433	insufficient statistics

Table 2. Articles Rejected from Meta-analysis

	Reason for Exclusion
Hanefield M Fischer S Schmechel H et al. Diabetes Intervention Study. Multi-intervention trial in newly diagnosed NIDDM. *Diabetes Care.* 1991;14(4):308. Rec #: 2595	no usual care or comparable control group
Hassell J, Medved E. Group/audiovisual instruction for patients with diabetes. *Journal of the American Dietetic Association.* 1975;5:465-470. Rec #: 2121	no glucose or weight outcomes reported
Hoskins PL Fowler PM Constantino M et al. Sharing the care of diabetic patients between hospital and general practitioners: does it work? *Diabetic Medicine.* 1993;10(1):81. Rec #: 2597	no usual care or comparable control group
Kaplan, Wilson, Hartwell/Merino, Wallace. Prospective evaluation of HDL changes after diet and physical conditioning programs for patients with Type II diabetes mellitus. *Diabetes Care.* 1985;8:343-48. Rec #: 2817	insufficient statistics
Kaplan RM, Hartwell SL, Wilson KD, Wallace JP. Effects of diet and exercise interventions on control and quality of life in non-insulin dependent diabetes mellitus. *J Gen Intern Med.* 1987;2:220-227. Rec #: 2175	insufficient statistics
Kendall PA, Jansen GR. Educating patients with diabetes: comparison of nutrient-based and exchanged group methods. *J Am Diet Assoc.* 1990;90:238-243. Rec #: 2207	no usual care or comparable control group
Kinmonth AL Woodcock A Griffin S et al. Randomised controlled trial of patient centred care of diabetes in general practice: impact on current wellbeing and future disease risk. The Diabetes Care From Diagnosis Research Team. *British Medical Journal.* 1998;317(7167):1202. Rec #: 2599	no usual care or comparable control group
Kumana CR/Ma JT, Kung A, Kou M, Lauder I. An assessment of drug information sheets for diabetic patients: Only active involvement by patients is helpful. *Diabetes Research and Clinical Practice.* 1988;5:225-231. Rec #: 2130	no glucose or weight outcomes reported
Litzelman D K, Slemenda C W, Langefeld C D, Hays L M, Welch M A, Bild D E, et al. Reduction of lower extremity clinical abnormalities in patients with non-insulin-dependent diabetes mellitus. A randomized, controlled trial. *Ann Intern Med.* 1993;119(1):36-41. Rec #: 828	no glucose or weight outcomes reported
Mazzuca SA, Moorman NH, Wheeler ML, Norton JA, Fineberg NS, Vinicor F, et al. The diabetes education study: A controlled trial of the effects of diabetes patient education. *Diabetes Care.* 1986;9:1-10. Rec #: 2132	duplicate data (Vinicor, 1987)
Mulrow C, Bailey S, Sonksen PH, Slavin B. Evaluation of an audiovisual diabetes education program: Negative results of a randomized trial of patients with non-insulin dependent diabetes mellitus. *Journal of General Medicine.* 1987;2:215-219. Rec #: 2266	no usual care or comparable control group
Pratt C, Wilson W, Leklem J, Kingsley L. Peer support and nutrition education for older adults with diabetes. *Journal of Nutrition for the Elderly.* 1987;6:37-43. Rec #: 2139	follow-up time not 3-12 months
Rabkin SW, Boyko E, Wilson A, Sreja DA. A randomized clinical trial comparing behavior modification and individual counseling in the nutritional therapy of non-insulin-dependent diabetes mellitus: comparison of the effect on blood sugar, body weight, and serum lipids. *Diabetes Care.* 1983;6:50-56. Rec #: 2195	no usual care or comparable control group
Rainwater N, Ayllon T, Frederiksen LW, Moore EJ, Bonar JR. Teaching self-management skills to increase diet compliance in diabetics. In: Stewart RB (Ed.). *Adherence, Compliance and Generalization in Behavioral Medicine*. New York: Brunner/Mazel, 1982. pgs. 304-328. Rec #: 2140	no usual care or comparable control group

Table 2. Articles Rejected from Meta-analysis

	Reason for Exclusion
Rettig BA, Shrauger DG, Recker RP, Gallagher TF, Wiltse H. A randomised study of the effects of a home diabetes education program. *Diabetes Care.* 1986;9:173-178. Rec #: 2270	no glucose or weight outcomes reported
Sadur C N, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S, et al. Diabetes management in a health maintenance organization. Efficacy of care management using cluster visits [In Process Citation]. *Diabetes Care.* 1999;22(12):2011-7. Rec #: 1668	not RCT
Stevens J, Burgess MB, Kaiser Dl, Sheppa CM. Outpatient management of diabetes mellitus with patient education to increase carbohydrate and fiber. *Diabetes Care.* 1985;8:359-366. Rec #: 2208	no usual care or comparable control group
Vinicor F, Cohen S J, Mazzuca S A, Moorman N, Wheeler M, Kuebler T, et al. DIABETES: a randomized trial of the effects of physician and/or patient education on diabetes patient outcomes. *J Chronic Dis.* 1987;40(4):345-56. Rec #: 892	follow-up time not 3-12 months
Ward WK, Haas LB, Beard JC. A randomized, controlled comparison of instruction by a diabetes educator versus self-instruction in self-monitoring of blood glucose. *Diabetes Care.* 1985;8:284-286. Rec #: 2152	no usual care or comparable control group
Werdier JD, Jesdinsky HJ, Helmich P. A randomized controlled study on the effect of diabetes counseling in the offices on 12 general practitioners. *Rev Epidemiol Med Sante Publique .* 1984;32:225-229. Rec #: 2401	not RCT
Wheeler LA, Wheeler ML, Ours P, Swider C. Evaluation of computer-based diet education in persons with diabetes mellitus and limited educational background. Diabetes Care 1985;8(6):537-44. Rec #: 3442	follow-up time not 3-12 months
Wilson W, Pratt C . The impact of diabetes education and peer support upon weight and glycemic control of elderly persons with non-insulin dependent diabetes mellitus (NIDDM). *Am J Public Health.* 1987;77(5):634-5. Rec #: 900	duplicate data (Pratt, 1987)
Wing RR, Epstein LH, Nowalk MP, Koeske R, Hagg S. Behavior change, weight loss and physiological improvements in Type II diabetic patients. *Journal of Consulting and Clinical Psychology.* 1985;53:11-122. Rec #: 2156	no usual care or comparable control group
Wing RR, Epstein LH, Nowalk MP, Scott N, Koeske R, Hagg S. Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with Type II diabetes? *the American Journal of Medicine.* 1986;81:830-836. Rec #: 2158	no usual care or comparable control group
Wing RR, Epstein LH, Nowalk MP, Scott N, Koeski R. Self-regulation in the treatment of Type II diabetes. *Behavior Therapy.* 1988;19:11-23. Rec #: 2283	no usual care or comparable control group
Wise PH, Dowlatshahi DC, Farrant S, Fromson SS/Meadows KA. Effect of computer-based learning on diabetes knowledge and control. *Diabetes Care.* 1986;9:504-508. Rec #: 2205	not RCT
Wood ER. Evaluation of a hospital-based education program for patients with diabetes. *Journal of the American Dietetic Association.* 1989;89:354-358. Rec #: 2159	not RCT
Worth R, Home PD, Johston DG, Anderson J, Ashworth L, Burrin JM, et al. Intensive attention improves glycemic control in insulin-dependent diabetes without further advantage from home glucose monitoring: results of a controlled trial. *BMJ.* 1982;285:1233-1240. Rec #: 2198	no usual care or comparable control group

Table 2. Articles Rejected from Meta-analysis

	Reason for Exclusion
Osteoarthritis	
Cohen J L, Sauter S V, deVellis R F, deVellis B M . Evaluation of arthritis self-management courses led by laypersons and by professionals. *Arthritis Rheum.* 1986;29(3):388-93. Rec #: 770	insufficient statistics
Doyle TH, Granada JL. Influence of two management approaches on the health status of women with osteoarthritis. *Arthritis and Rheumatism.* 1982;25:S56. Rec #: 2427	no usual care or comparable control group
Keefe F, Caldwell D, Baucom D, et al. Spouse-assisted coping skills training in the management of osteoarthritis knee pain. *Arthritis Care and Research.* 1996;9:279. Rec #: 2082	no usual care or comparable control group
Keefe F J, Caldwell D S, Williams D A, Gil K M, et al. Pain coping skills training in the management of osteoarthritic knee pain: A comparative study. *Behavior Therapy.* 1990b;21:49-62. Rec #: 908	duplicate populations (Keefe, 1990a)
Laborde JM, Powers MJ. Evaluation of education interventions for osteoarthritics. *Multiple Linear Reg Viewpoints.* 1983;12:12-37. Rec #: 2355	insufficient statistics
Weinberger M, Tierney W M, Booher P, Katz B P . Can the provision of information to patients with osteoarthritis improve functional status? A randomized, controlled trial. *Arthritis Rheum.* 1989;32(12):1577-83. Rec #: 430	duplicate data (Weinberger, 1991)
Weinberger M, Tierney W M, Booher P, Katz B P . The impact of increased contact on psychosocial outcomes in patients with osteoarthritis: a randomized, controlled trial. *J Rheumatol.* 1991;18(6):849-54. Rec #: 898	insufficient statistics

Table 2. Articles Rejected from Meta-analysis

Post-Myocardial Infarction Care Articles	Reason for Exclusion
DeBusk RF, Miller NH, Superko HR, Dennis CA, Thomas RJ, Lew HT, et al. A case-management system for coronary risk factor modification after acute myocardial infarction [see comments]. *Ann Intern Med.* 1994;120(9):721-9. Rec #: 775	no usual care or comparable control group
Frasure-Smith N, Prince R . The ischemic heart disease life stress monitoring program: impact on mortality. *Psychosom Med.* 1985;47(5):431-45. Rec #: 790	not RCT
Frasure-Smith N, Prince R. Long-term follow-up of the ischemic heart disease life stress monitoring program. *Psychosom Med.* 1989;51:485-513. Rec #: 2218	not RCT
Friedman M, Thoresen C, Gill JJ, Ulmer DK. Feasibility of altering Type A behavior pattern after myocardial infarction: Recurrent coronary prevention project study: Methods, baseline results and preliminary findings. *Circulation.* 1982;66:83-92. Rec #: 2367	not RCT
Friedman M, Thoresen CE, Gill JJ, et al. Alteration of Type A behavior and reduction in cardiac recurrences in postmyocardial infarction patients. *Am Heart J.* 1984;108:237-248. Rec #: 2362	no usual care or comparable control group
Gruen W. Effects of brief psychotherapy during the hospitalization period on the recovery process in heart attacks. *J Consulting Clinical Psychology.* 1975;43:223-232. Rec #: 2360	not RCT
Lewin B, Robertson I H, Cay E L, Irving J B, Campbell M . Effects of self-help post-myocardial-infarction rehabilitation on psychological adjustment and use of health services. *Lancet.* 1992;339(8800):1036-40. Rec #: 827	insufficient statistics
Miller NH, Haskell WL, Berra K et al. Home versus group exercise training for increasing functional capacity after myocardial infarction. *Circulation.* 1984;4:645-649. Rec #: 2670	insufficient statistics
Oldenburg B, Allan R, Fastier G. The role of behavioral and educational interventions in the secondary prevention of coronary heart disease. *In P.F. Lovibond & P.H. Wilson (Eds), Clinical and Abnormal Psychology Proceedings of the XXIV International Congress of Psychology of the International Union of Psychological Science.* 1989:429-438. Rec #: 2698	insufficient statistics
Oldenburg B, Perkins RJ, Andrews G. Controlled trial of psychological intervention in myocardial infarction. *Journal of Consulting and Clinical Psychology.* 1985;53:852-859. Rec #: 2699	not RCT
Ott CR, Sivarajan ES, Newton KM et al. A controlled randomized study of early cardiac rehabilitation: the Sickness Impact Profile as an assessment tool. *Heart Lung.* 1983;12:162-170. Rec #: 2657	insufficient statistics
Payne T J, Johnson C A, Penzien D B, Porzelius J, Eldridge G, Parisi S, et al. Chest pain self-management training for patients with coronary artery disease. *J Psychosom Res.* 1994;38(5):409-18. Rec #: 859	not RCT
Powell LH, Friedman M, Thoresen CE, Gill JJ, Ulmer DK. Can the Type A behavior pattern be altered after myocardial infarction? A second year report from the Recurrent Coronary Prevention Project. *Psychosom Med.* 1984;46(4):293-313. Rec #: 2361	no usual care or comparable control group
Schulte MB, Pluym B, Van Schendel G. Reintegration with duos: A self-care program following myocardial infarction. *Patients Education and Counseling.* 1986;8:233-244. Rec #: 2438	not RCT

Table 2. Articles Rejected from Meta-analysis

	Reason for Exclusion
Sivarajan ES, Bruce RA, Lindskog BD, et al. Treadmill test responses to an early exercise program after myocardial infarction: a randomized study. *Circulation.* 1982;65:1420. Rec #: 3248	duplicate population (Froelicher, 1994)
Sivarajan ES, Newton KM, Almes MJ, et al. Limited effects of outpatient teaching and counseling after myocardial infarction: A controlled study. *Heart and Lung.* 1983;12:65-73. Rec #: 2439	insufficient statistics
Turner L, Linden W, van der Wal R, Schamberger W . Stress management for patients with heart disease: a pilot study. *Heart Lung.* 1995;24(2):145-53. Rec #: 887	no mortality or return to work outcomes reported
Hypertension Articles	
Irvine MJ, Johnson DW, Jenner DA, et al. Relaxation and stress management in the treatment of essential hypertension. *J of Psychosomatic Res.* 1986;30:437-450. Rec #: 2458	no usual care or comparable control group
Leveille SG, Wagner EH, Davis C, Grothaus L, Wallace J, LoGerfo M, et al. Preventing disability and managing chronic illness in frail older adults: A randomized trial of a community-based partnership with primary care. *JAGS.* 1998;46(10):1-9. Rec #: 1175	insufficient statistics
Levine DM, Green LW, Deeds SG, Chwalow J, Russell RP, Finlay J. Health education for hypertensive patients. *JAMA* 1979;241:1700-1703. Rec #: 3453	insufficient statistics
Martinez-Amenos A, Ferre LF, Vidal CM, Rocasalbas JA. Evaluation of two educative models in a primary care hypertension programme. *Journal of Human Hypertension* 1990;4:362-4. Rec #: 3457	insufficient statistics
Morisky DE, Levine DM, Green LW, Russell RP, Smith C, Benson P, et al. The relative impact of health education for low- and high-risk patients with hypertension. *Prev Med* 1980;9(4):550-8. Rec #: 3461	insufficient statistics
Morisky DE, Levine DM, Green LW, et al. Five-year blood pressure control and mortality following health education for hypertensive patients. *Am J Public Health.* 1983;73(2):153-162. Rec #: 2304	insufficient statistics

Table 3. Diabetes articles Contributing to Meta-analysis	Weight	Hemoglobin A1c	Blood Glucose
D'Eramo-Melkus GA, Wylie-Rosett J, Hagan JA. Metabolic impact of education in NIDDM . *Diabetes Care.* 1992;18:864-869. Rec #: 2202	X	X	X
Falkenberg MG, Elwing BE, Goransson AM, Hellstrand BE, Riis UM. Problem oriented participatory education in the guidance of adults with non-insulin-treated type II diabetes mellitus. *Scand J Prim Health Care.* 1986;4:157-164. Rec #: 2190		X	
Frost G, Wilding J, Beecham J . Dietary advice based on the glycemic index improves dietary profile and metabolic control in type 2 diabetic patients. *Diabet Med.* 1994;11(4):397-401. Rec #: 791	X		X
Glasgow RE, Toobert DJ, Hampson SE, Brown JE, Lewinsohn PM, Donnelly J. Improving self-care among older patients with type II diabetes: the "sixty something...." study. *Patient Educ Couns.* 1992;19:61-74. Rec #: 2212	X	X	
Greenfield S, Kaplan S H, Ware J E, Yano E M, Frank H J . Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med.* 1988;3(5):448-57. Rec #: 803		X	
Jaber LA Halapy H Fernet M et al. Evaluation of a pharmaceutical care model on diabetes management. *Annals of Pharmacotherapy.* 1996;30(3):238. Rec #: 2598		X	X
Jennings PE, Morgan HC, Barnett AH. Improved diabetes control and knowledge during a diabetic self-help group. *The Diabetes Educator.* 1987;13:390-393. Rec #: 2126		X	
Korhonen T, Huttnen JK, Aro A, Hentinen M, Ihalainen O, Majander H, et al. A controlled trial of the effects of patient education in the treatment of insulin dependent diabetes. *Diabetes Care.* 1983;6:256-261. Rec #: 2259			X
Laitinen JH, Ahola IE, Sarkkinen ES, Winberg RL, Harmaakorpi-Ilvonen PA, Usitupa MI. Impact of intensified dietary therapy on energy and nutrient intakes and fatty acid composition of serum lipids in patients with recently diagnosed non-insulin-dependent diabetes mellitus. *J Am Diet Assoc.* 1993;93:276-283. Rec #: 2176	X	X	X
McCulloch DK, Mitchell RD, Ambler J, Tattersall RB. Influence of imaginative teaching of diet on compliance and metabolic control in insulin dependent diabetes. *British Medical Journal.* 1983;28:1858-1861. Rec #: 2264	X	X	
Raz I, Soskolne V, Stein P. Influence of small-group education sessions on glucose homeostasis in NIDDM. *Diabetes Care.* 1988;11:67-71. Rec #: 2141	X	X	X
Vanninen E, Uuspitupa M, Siitonen O, Laitinen J, Lansimies E. Habitual physical activity, aerobic capacity and metabolic control in patients with newly-diagnosed type 2 (non-insulin-dependent) diabetes mellitus: effect of 1-year diet and exercise intervention. *Diabetologia.* 1992;35:340-346. Rec #: 2174	X	X	X
Weinberger M, Kirkman M S, Samsa G P, Shortliffe E A, Landsman P B, Cowper P A, et al. A nurse-coordinated intervention for primary care patients with non- insulin-dependent diabetes mellitus: impact on glycemic control and health-related quality of life [see comments]. *J Gen Intern Med.* 1995;10(2):59-66. Rec #: 896		X	X
White N, Carnahan J, Nugent CA, Iwaoka T, Dodsono MA. Management of obese patients with diabetes mellitus: comparison of advice education with group management. *Diabetes Care.* 1986;9:490-496. Rec #: 2154	X	X	X
Total number of studies	8	12	9

Table 4. Osteoarthritis Articles Contributing to Meta-analysis

Barlow JH, Turner AP, Wright CC. A randomized controlled study of the Arthritis Self-Management Programme in the UK. Health Educ Res. 2000;15(6):665-80. Rec #: 3274
Goeppinger J, Arthur M W, Baglioni A J, Brunk S E, Brunner C M . A reexamination of the effectiveness of self-care education for persons with arthritis. *Arthritis Rheum.* 1989;32(6):706-16. Rec #: 801
Keefe F J, Caldwell D S, Williams D A, Gil K M, et al. Pain coping skills training in the management of osteoarthritic knee pain-II: Follow-up results. *Behavior Therapy.* 1990a;21:435-447. Rec #: 907
Lorig K, Feigenbaum P, Regan C, Ung E, Chastain R L, Holman H R . A comparison of lay-taught and professional-taught arthritis self- management courses. *J Rheumatol.* 1986;13(4):763-7. Rec #: 830
Lorig K, Lubeck D, Kraines R G, Seleznick M, Holman H R . Outcomes of self-help education for patients with arthritis. *Arthritis Rheum.* 1985;28(6):680-5. Rec #: 835
Lorig K, Seleznick M, Lubeck D, Ung E, Chastain R L, Holman H R . The beneficial outcomes of the arthritis self-management course are not adequately explained by behavior change. *Arthritis Rheum.* 1989;32(1):91-5. Rec #: 837
Lorig K R, Sobel D S, Stewart A L, Brown Jr B W, Bandura A, Ritter P, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: A randomized trial. *Medical Care.* 1999;37(1):5-14. Rec #: 608

All articles contributed both pain and function outcomes.

Table 5. Post-Myocardial Infarction Care Articles Contributing to Meta-analysis

	Death	Return to Work
Burgess AW, Lerner DJ D'Agostino RB, Vokonas PS, Hartman CR, Gaccione P. A randomized control trial of cardiac rehabilitation. *Soc Sci Med.* 1987;24:359-370. Rec #: 2652	X	X
DeBusk F, Haskell WL, Miller NN et al. Medically directed at-home rehabilitation soon after clinically uncomplicated acute myocardial infarction: a new mode for patient care. *Am J Cardio.* 1985;85:251-257. (in MA for mortality only) Rec #: 2669	X	
Dennis C, Houston-Miller N, Schwartz RG et al. Early return to work after uncomplicated myocardial infarction. *JAMA.* 1988;260:214-220. Rec #: 2656	X	X
Froelicher E S, Kee L L, Newton K M, Lindskog B, Livingston M . Return to work, sexual activity, and other activities after acute myocardial infarction. *Heart Lung.* 1994;23(5):423-35. Rec #: 792	X	X
Heller R F, Knapp J C, Valenti L A, Dobson A J . Secondary prevention after acute myocardial infarction. *Am J Cardiol.* 1993;72(11):759-62. Rec #: 809	X	X
Horlick L, Cameron R, Firor W, et al . The effects of education and group discussion in the postmyocardial infarction patient. *J Psychosom Res.* 1984;28:485-492. Rec #: 2219	X	X
Oldridge N, Guyatt G, Jones N. Effects of quality of life with comprehensive rehabilitation after acute myocardial infarction. *Am J Cardiol.* 1991;67:1084-1089. Rec #: 2653	X	X
Rahe RM, Ward HW, Hayes V. Brief group therapy in myocardial infarction rehabilitation: Three to four year follow-up of a controlled trial . *Psychosom Med.* 1979;41:229-242. Rec #: 2406	X	X
Stern MJ, Gorman PA, Kaslow . The group counseling vs. exercise therapy study: A controlled intervention with subjects following myocardial infarction. *Arch Intern Med.* 1983;143:1719-1725. Rec #: 2377	X	X
Total number of studies	9	8

Table 6. Hypertension Articles Contributing to Meta-analysis
Blumenthal JA, Siegel WC, Appelbaum M . Failure of exercise to reduce blood pressure in patients with mild hypertension. Results of a randomized controlled trial [see comments]. *JAMA.* 1991;266(15):2098-104. Rec #: 752
Given C, Given B, Coyle B. The effects of patient characteristics and beliefs on responses to behavioral interventions for control of chronic diseases. *Pat Ed Counsel.* 1984;6(3):131-140. Rec #: 2309
Goldstein IB, Shapiro D, et al. Comparison of drug and behavioral treatments of essential hypertension. *Health Psychology.* 1982;1:7-26. Rec #: 2466
Gonzalez-Fernandez RA, Rivera M, Torres D, Quiles J, Jackson A. Usefulness of a systemic hypertension in-hospital program. *The American Journal of Cardiology* 1990;65:1384-1386. Rec #: 3451
Hafner RJ. Psychological treatment of essential hypertension: A controlled comparison of meditation and medication plus biofeedback. *Biofeedback and Self-Regulation.* 1982;7:305-315. Rec #: 2467
Hoelscher TJ, Lichstein KL, Fischer S, et al. Home relaxation practice in hypertension treatment: Objective assessment and compliance induction. *J of Consulting and Clinical Psychology.* 1986;54:217-221. Rec #: 2457
Jacob RG, Fortmann SP, Kraemer HC, et al. Combining behavioral treatments to reduce blood pressure: A controlled outcome study. *Behavior Modification.* 1985;9:32-45. Rec #: 2459
Jorgensen RS, Houston BK, Zurawski RM. Anxiety management training in the treatment of essential hypertension. *Behavior Research and Therapy.* 1981;19:467-474. Rec #: 2452
Kostis JB, Rosen RC, Brondolo E, et al. Superiority of nonpharmacologic therapy compared to propranolol and placebo in men with mild hypertension: A randomised prospective trial. *American Heart Journal.* 1992;123:466-474. Rec #: 2472
Lagrone R, Jeffrey TB, Ferguson CL. Effects of education and relaxation training with essential hypertension patients. *J of Clinical Psychology.* 1988;44:271-276. Rec #: 2460
Muhlhauser I, Sawicki PT, Didjurgeit U, Jorgens V, Trampisch HJ, Berger M. Evaluation of a structured treatment and teaching programme on hypertension in general practice. *Clin Exp Hypertens* 1993;15(1):125-42. Rec #: 3467
Southam MA, Agras WS, Taylor CB, et al. Relaxation training: Blood pressure lowering during the working day. *Archives of General Psychiatry.* 1982;39:715-717. Rec #: 2453
Taylor CB, Farquhar JW, Nelson E, et al. Relaxation therapy and high blood pressure. *Arch General Psychiatry.* 1977;34:339-342. Rec #: 2464
Watkins CJ, Papacosta AO, Chinn S, Martin J. A randomized controlled trial of an information booklet for hypertensive patients in general practice. *J R Coll Gen Pract* 1987;37(305):548-50. Rec #: 3469

All studies contributed to both systolic and diastolic blood pressure analyses.

RESULTS OF THE META-ANALYSES

Of the 14 questions posed by CMS, the following four could be most directly addressed via meta-analyses. Theses four questions are related and their results are presented together.

Question 1. Do these programs work?

Question 2. Are there features that are generalizable across all diseases?

Question 6. What is the impact of chronic disease self-management programs on quality of life, health status, health outcomes, satisfaction, pain, independence, mental health (e.g., depression, emotional problems)?

Question 10. Is a generic self-management approach preferable to a disease-by-disease approach?

The responses to these questions are presented in this section, by condition, (Diabetes, Osteoarthritis, Post-Myocardial Infarction Care and Hypertension). We then by report the results as they address our five hypotheses, both within condition and across conditions.

Diabetes

There were 14 comparisons from 12 studies that reported hemoglobin A1c outcomes. In an overall analysis of the effectiveness of chronic disease self-management programs, these studies reported a statistically and clinically significant pooled effect size of -0.45 in favor of the intervention (95% CI: (-0.26, -0.63); see Figure 6). The negative effect size indicates a lower hemoglobin A1c in the treatment group as compared to the usual care or control group. An effect size of –0.45 is equal to a reduction in hemoglobin A1c of about 1.0. For change in weight, there were 10 comparisons from 8 studies. There was no statistically significant

difference between change in weight in the intervention and control groups (effect size of -0.05; 95% CI:(-0.12, 0.23); see Figure 8). There were 10 comparisons from 9 studies that reported fasting blood glucose outcomes. The pooled effect size was -0.41 in favor of the intervention (95% CI: (-0.23, -0.60); see Figure 10). This effect size equates to a drop in blood glucose of 1 mml/l.

Our assessment of publication bias (graphically depicted in funnel plots in Figures 7, 9, and 11 and also presented in Table 7) revealed likely publication bias in studies reporting hemoglobin A1c outcomes. Therefore, our results regarding efficacy of chronic disease self-management programs for improving hemoglobin A1c must be interpreted with caution.

Figure 6. Forest Plot of Diabetes Studies: Hemoglobin A1c

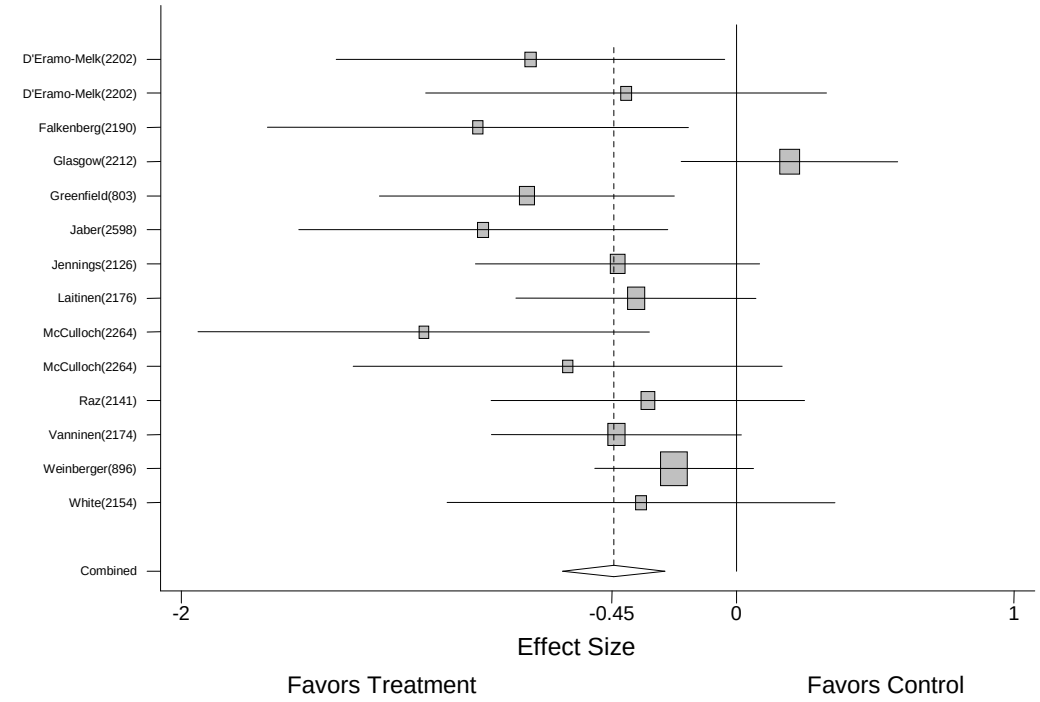


Figure 7. Funnel Plot of Diabetes Studies: Hemoglobin A1c

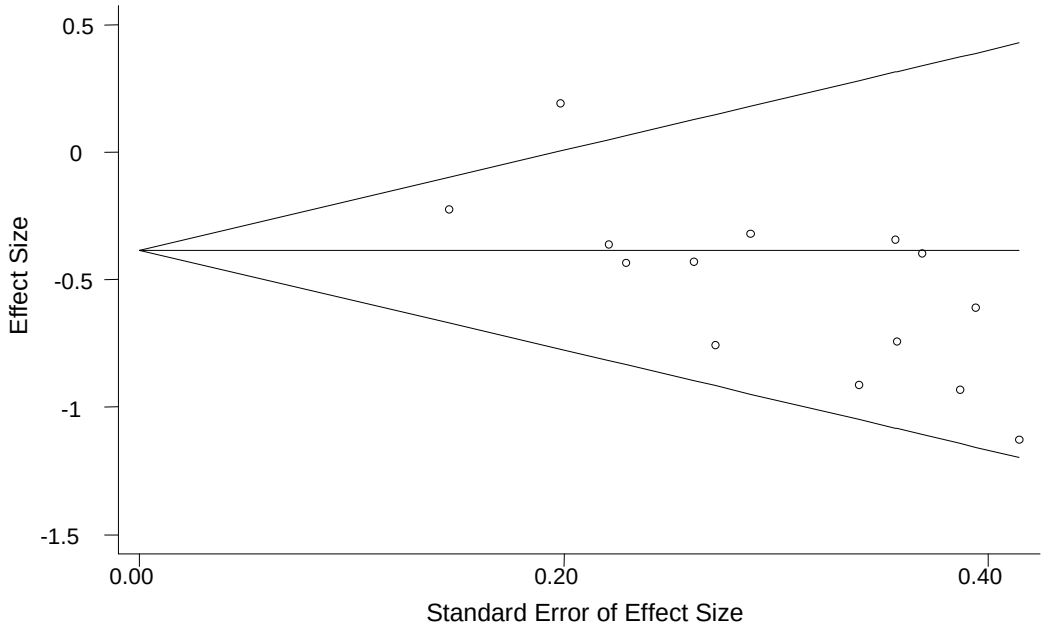


Figure 8. Forest Plot of Diabetes Studies: Weight

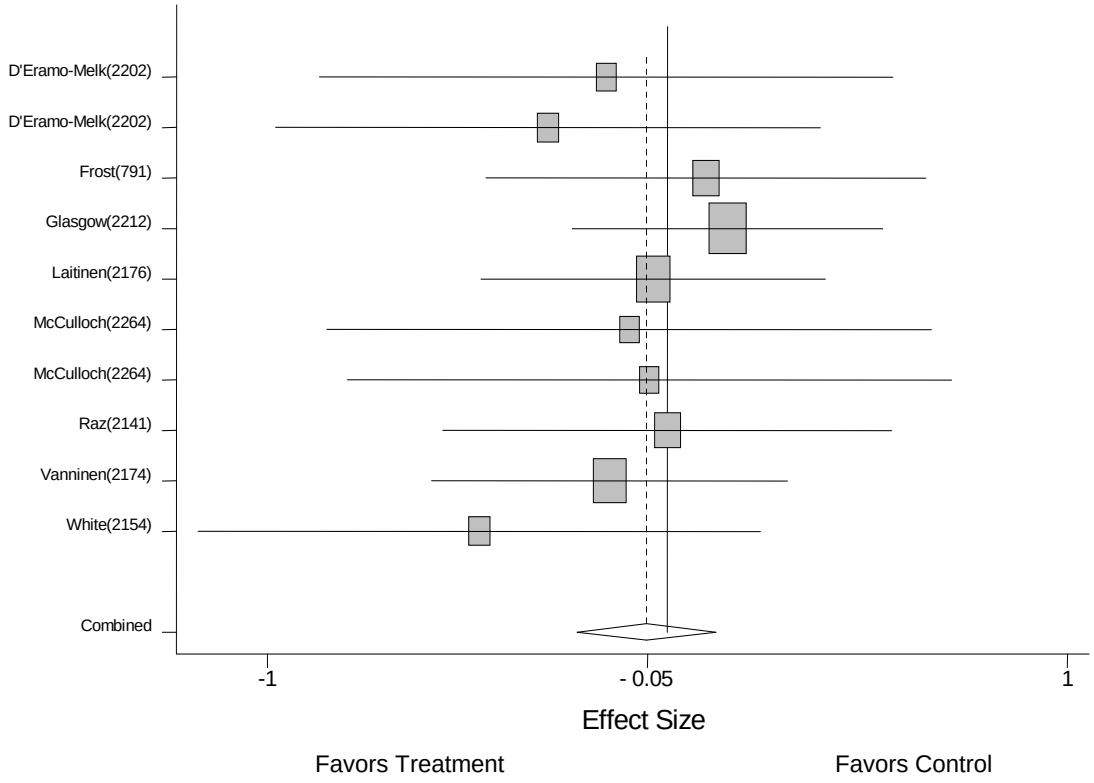


Figure 9. Funnel Plot of Diabetes Studies: Weight

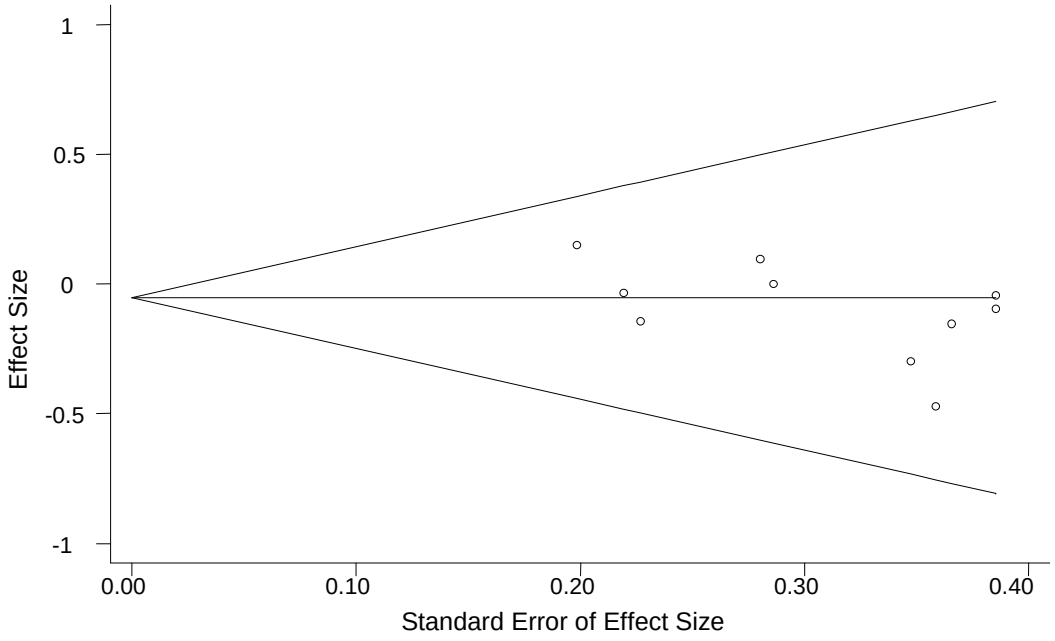


Figure 10. Forest Plot of Diabetes Studies: Fasting Blood Glucose

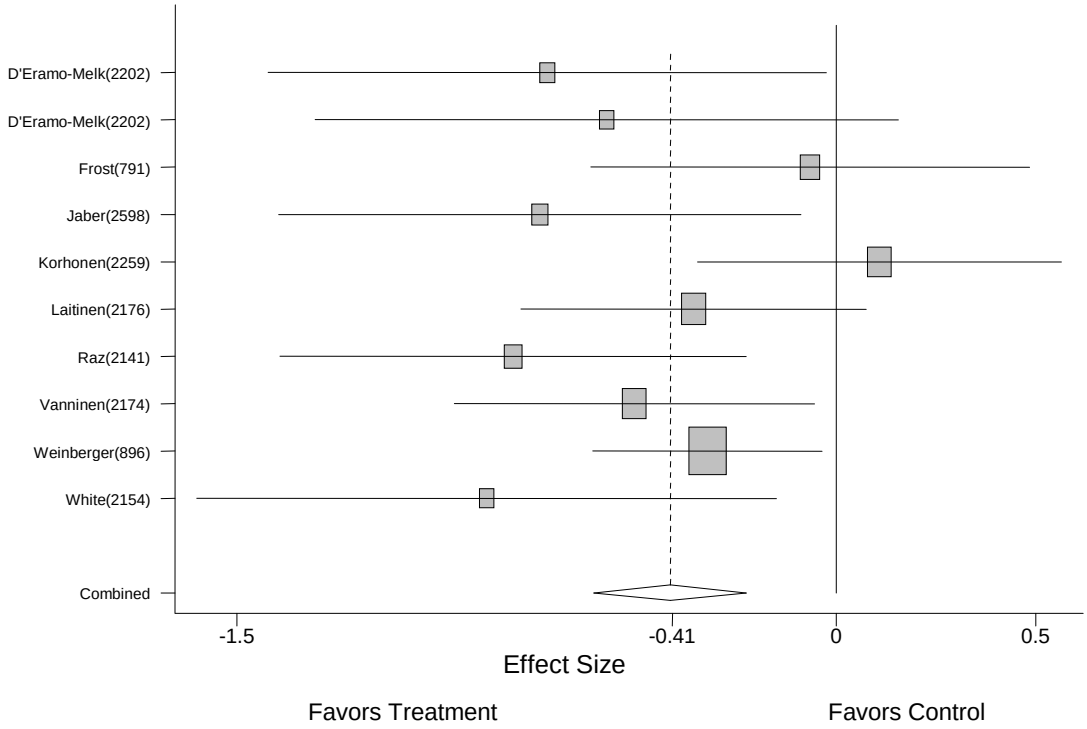


Figure 11. Funnel Plot of Diabetes Studies: Fasting Blood Glucose

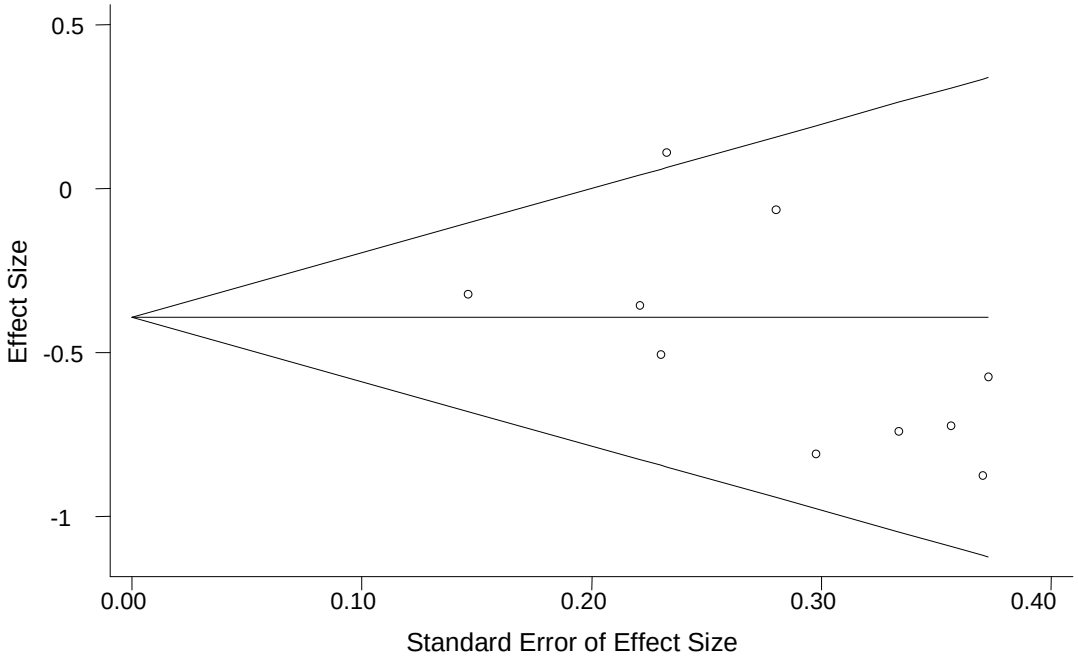


Table 7. Publication Bias for Diabetes Studies

Condition/ Outcome	# arms	Correlation Test (p-value)	Asymmetry Test (p-value)	# studies	Correlation Test (p-value)	Asymmetry Test (p-value)
Hemoglobin	14	0.016	0.006	12	0.011	0.008
Weight	10	0.210	0.079	8	0.108	0.090
Blood Glucose	10	0.210	0.136	9	0.118	0.177

Osteoarthritis

For both pain and function outcomes there were 10 comparisons from 7 different studies. The pooled results of these chronic disease self-management programs did not yield any statistically significant differences between intervention and control groups (pooled effect sizes of -0.04 and -0.01 for pain and function respectively; see Figures 12 and 14).

Our assessment of publication bias depicted graphically in Figures 13 and 15 and Table 8 did not yield any evidence of publication bias.

Figure 12. Forest Plot of Osteoarthritis Studies: Pain

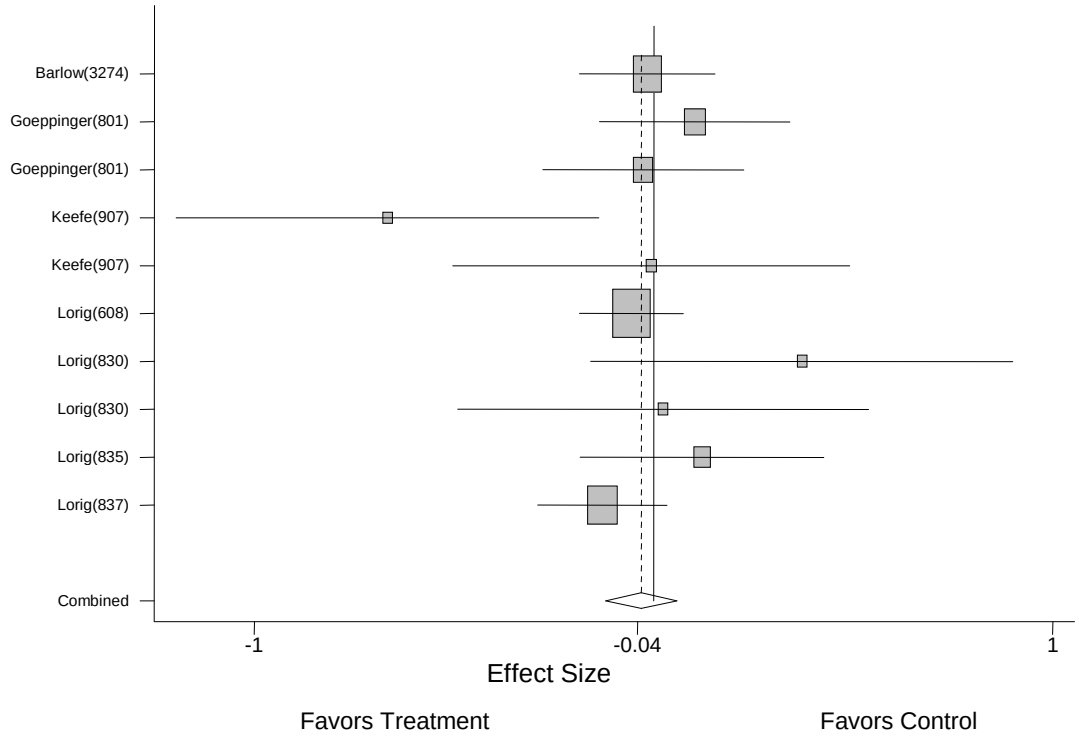


Figure 13. Funnel Plot of Osteoarthritis Studies: Pain

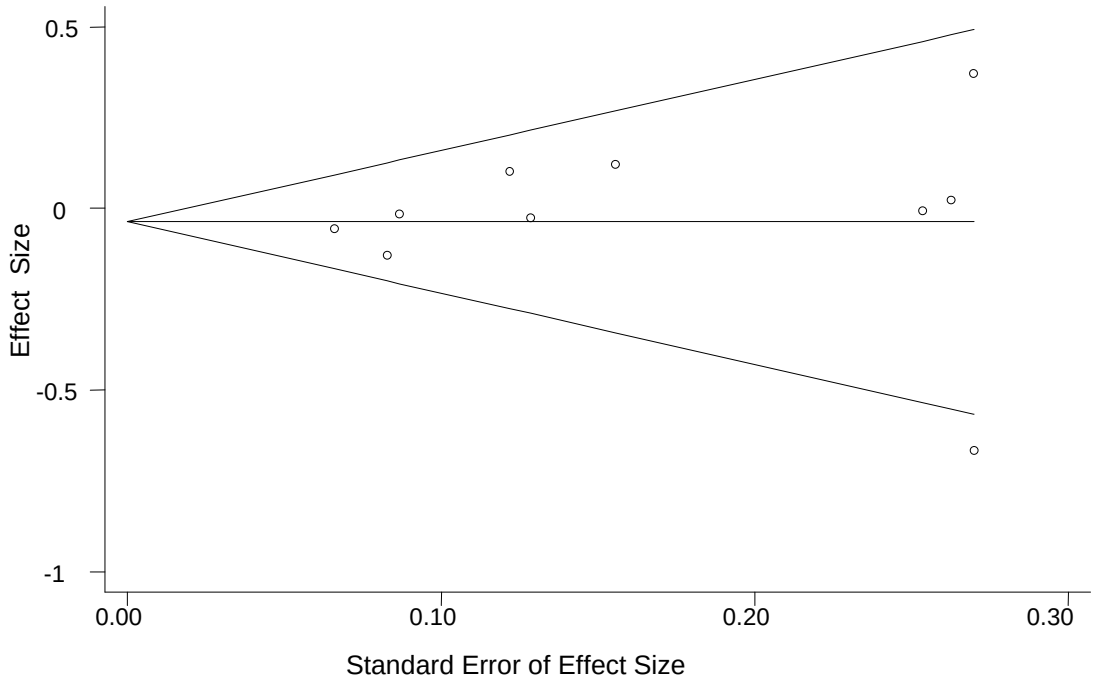


Figure 14. Forest Plot of Osteoarthritis Studies: Functioning

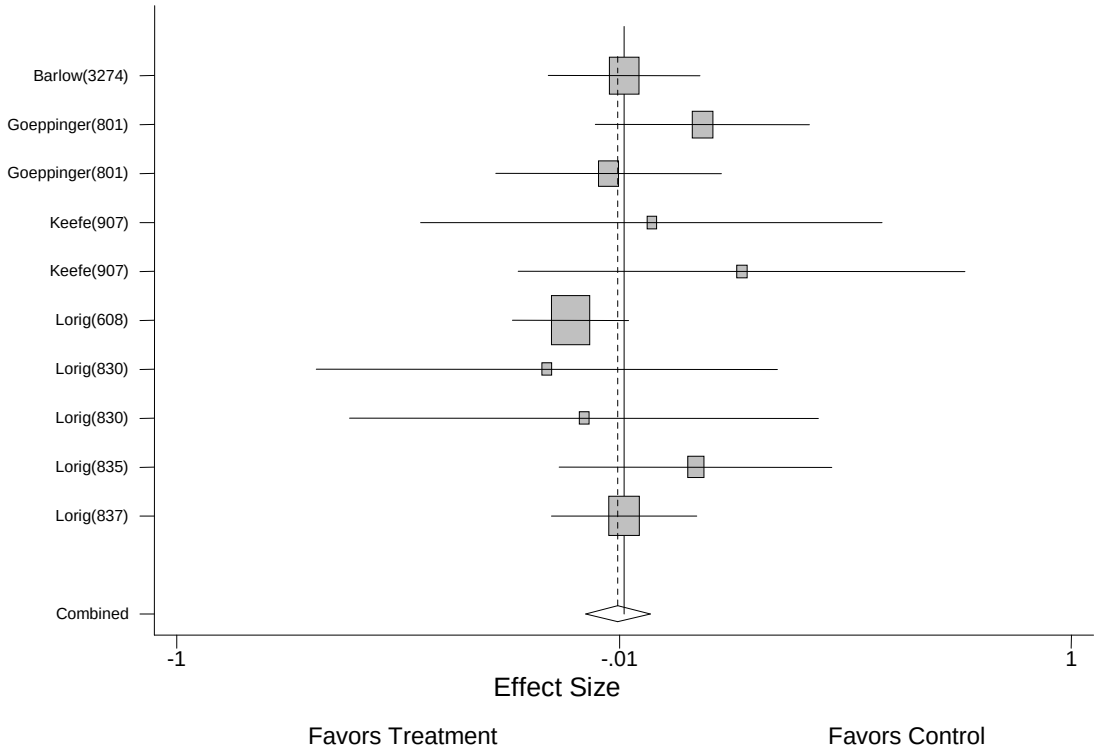


Figure 15. Funnel Plot of Osteoarthritis Studies: Functioning

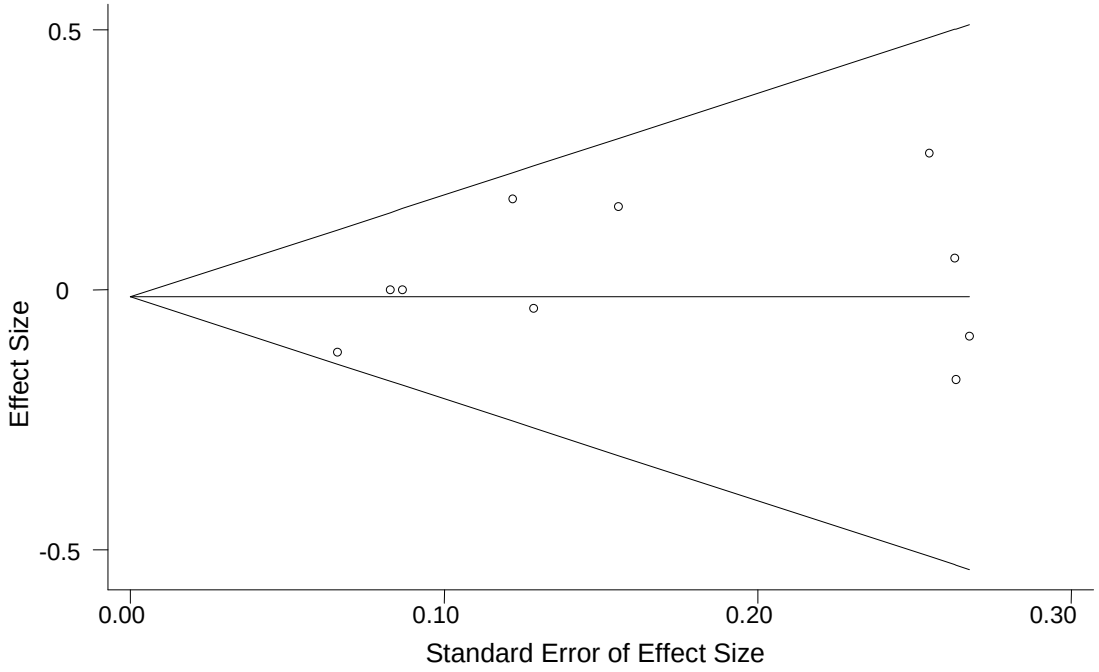


Table 8. Publication Bias for Osteoarthritis Studies

Condition/ Outcome	# arms	Correlation Test (p-value)	Asymmetry Test (p-value)	# studies	Correlation Test (p-value)	Asymmetry Test (p-value)
Pain	10	0.592	0.724	7	0.548	0.831
Functioning	10	0.788	0.230	7	0.764	0.337

Post Myocardial Infarction Care

There were 9 studies that reported mortality outcomes. There was no effect of chronic disease self-management programs on improving mortality (pooled relative risk 1.04; 95% CI: (0.56, 1.95); see Figure 16). For return to work there were 10 comparisons from 8 studies. The pooled relative risk did not show any difference between groups (relative risk 1.02; 95% CI: (0.97, 1.08); see Figure 18).

Our assessment of publication bias (Funnel Plots 17 and 19, and Table 9) showed evidence of publication bias for the mortality outcome but not the return to work outcome.

Figure 16. Forest Plot of Post-Myocardial Infarction Care Studies: Mortality

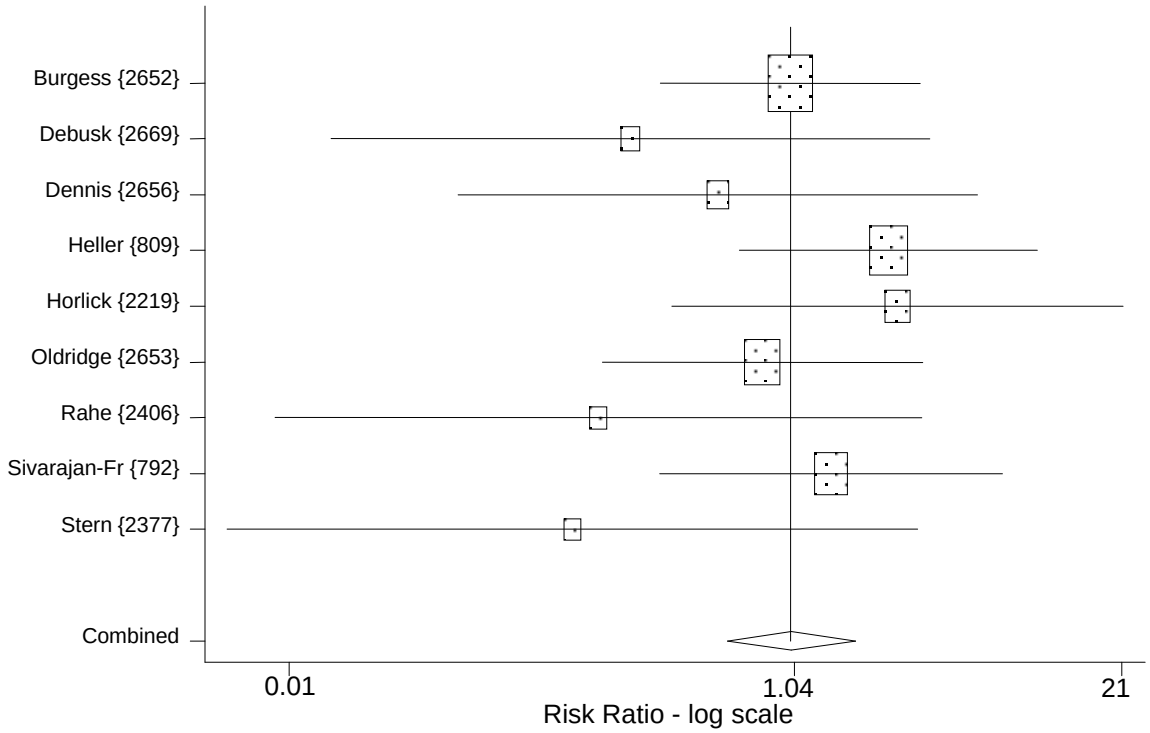


Figure 17. Funnel Plot of Post-Myocardial Infarction Care Studies: Mortality

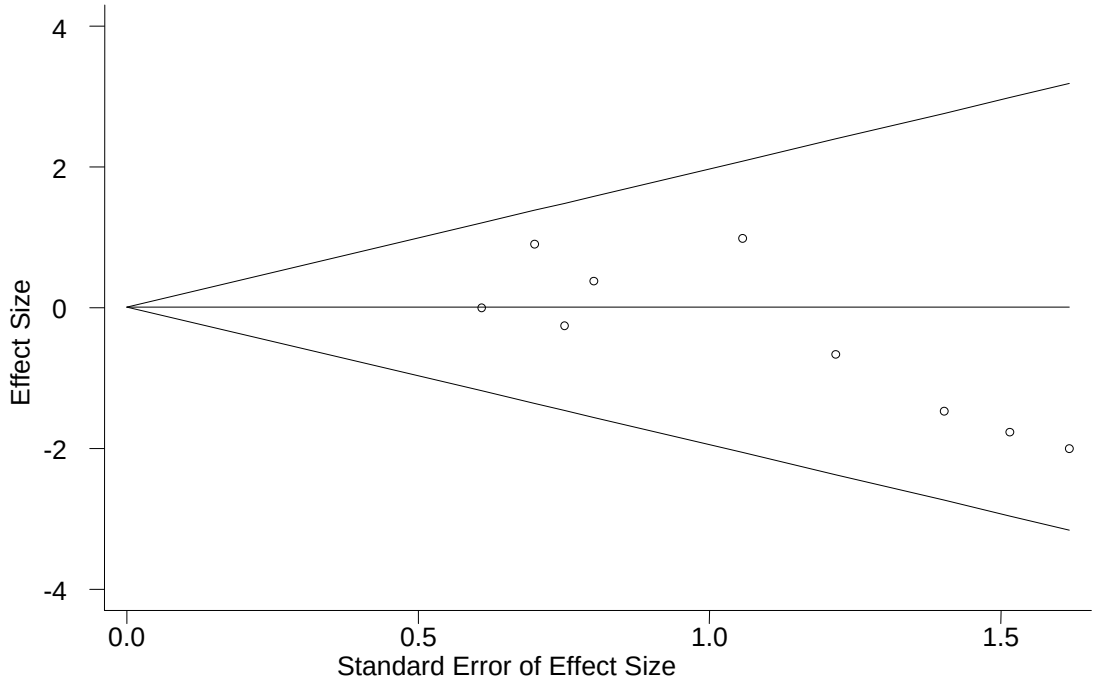


Figure 18. Forest Plot of Post-Myocardial Infarction Care Studies: Return to Work

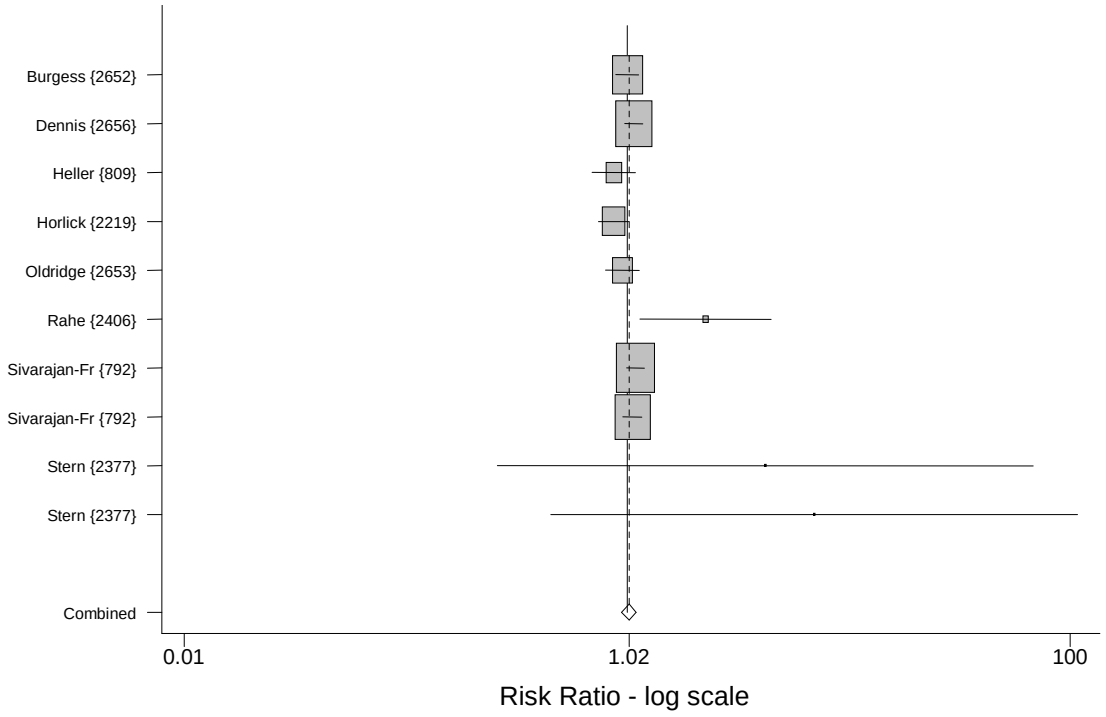


Figure 19. Funnel Plot of Post-Myocardial Infarction Care Studies: Return to Work

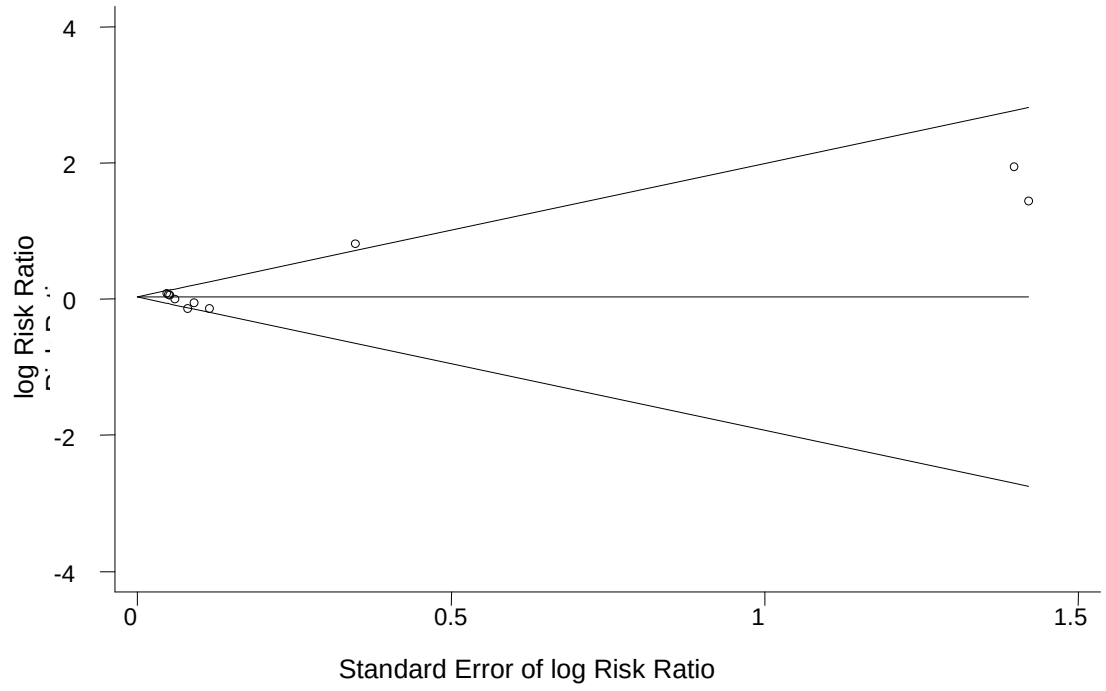


Table 9. Publication Bias for Post-Myocardial Infarction Care Studies

Condition/ Outcome	# arms	Correlation Test (p-value)	Asymmetry Test (p-value)	# studies	Correlation Test (p-value)	Asymmetry Test (p-value)
Mortality	15	0.012	0.005	9	0.076	0.087
Return to Work	10	1.000	0.450	8	0.902	0.641

Hypertension

For hypertension there were 23 comparisons from 14 studies that reported systolic and diastolic blood pressure changes. The overall pooled result of the chronic disease self-management programs was a statistically and clinically significant reduction in systolic and diastolic blood pressure (effect size for systolic blood pressure -0.32; 95% CI: (-0.50, -0.15); effect size for diastolic blood pressure -0.59; 95% CI: (-0.81, -0.38); see Figures 20 and 22). An effect size of 0.32 is equivalent to a change in blood pressure of 3.5 mm of mercury, the corresponding value for an effect size of 0.59 is 6.5 mm of mercury.

In our assessment of publication bias, (presented in Funnel Plots 21 and 23 and Table 10), there was evidence of publication bias. Therefore our pooled result favoring chronic disease self-management programs for hypertension must be viewed with caution.

Figure 20. Forest Plot of Hypertension Studies: Systolic Blood Pressure

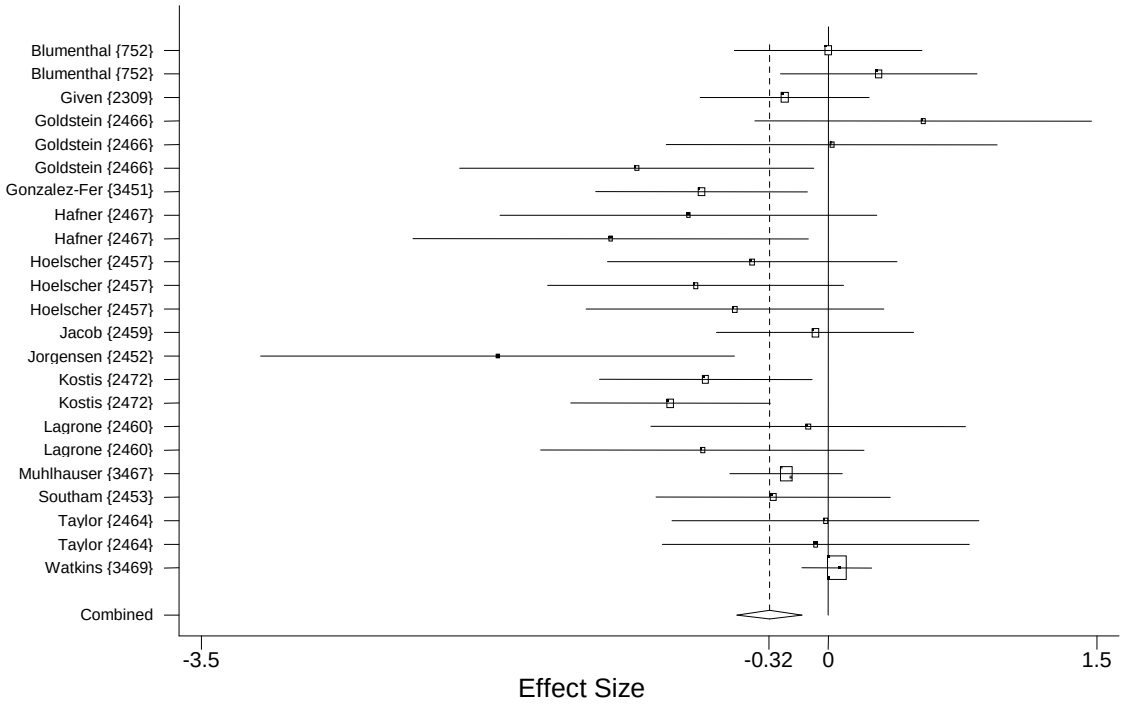


Figure 21. Funnel Plot of Hypertension Studies: Systolic Blood Pressure

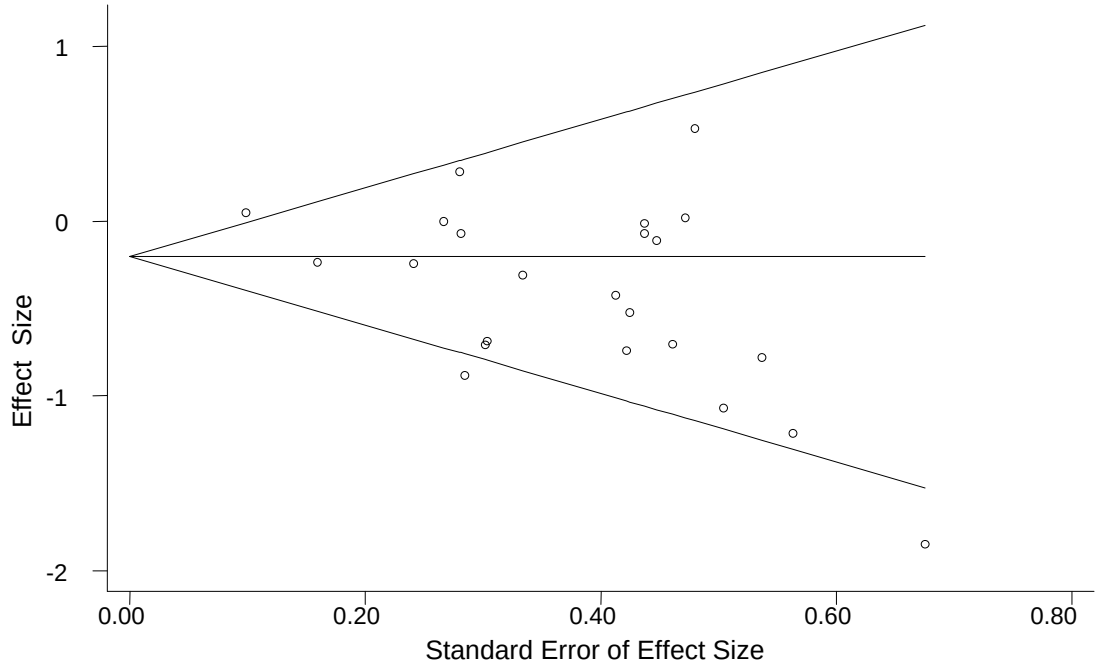


Figure 22. Forest Plot of Hypertension Studies: Diastolic Blood Pressure

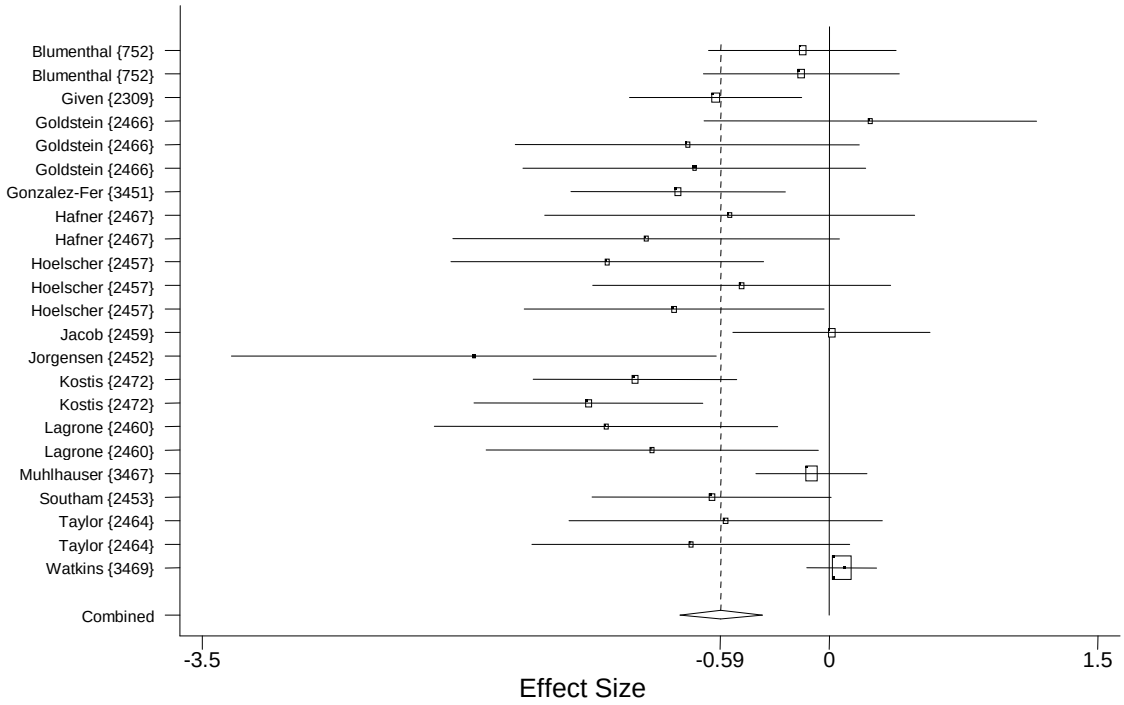


Figure 23. Funnel Plot of Hypertension Studies: Diastolic Blood Pressure

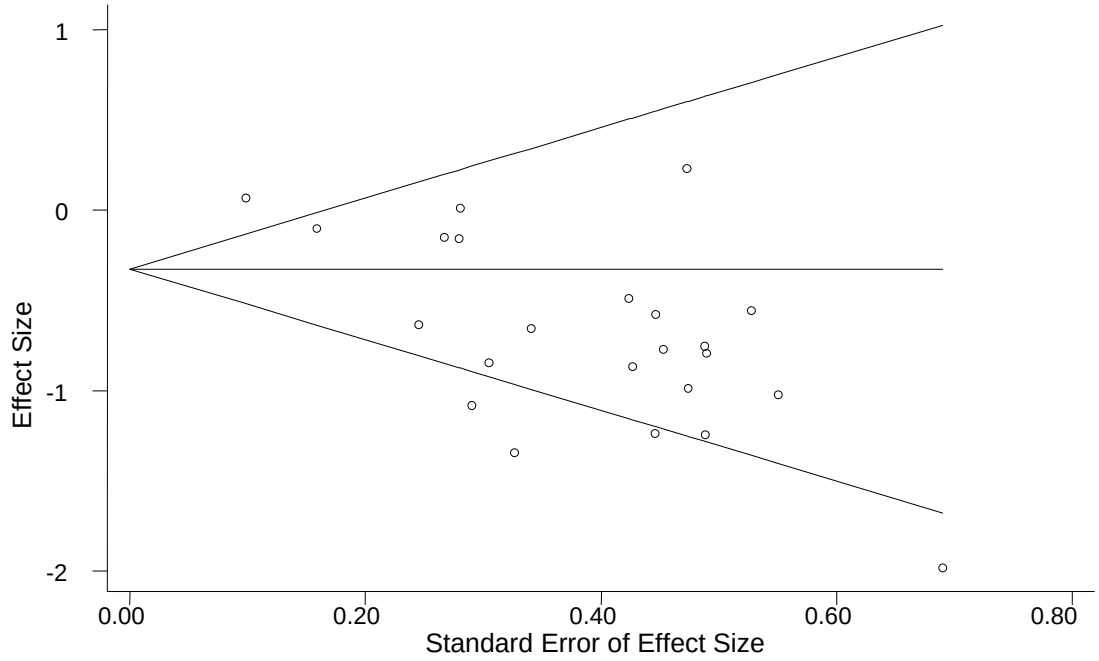


Table 10. Publication Bias for Hypertension Studies

Condition/ Outcome	# arms	Correlation Test (p-value)	Asymmetry Test (p-value)	# studies	Correlation Test (p-value)	Asymmetry Test (p-value)
Systolic BP	20	0.074	0.077	11	0.008	0.021
Diastolic BP	20	0.074	0.045	11	0.043	0.017

Overall Analysis

For the three conditions that reported continuous outcomes (diabetes, osteoarthritis and hypertension) we chose the one outcome from each study that we judged most clinically relevant (hemoglobin A1c, pain, and systolic blood pressure, respectively) and used this to perform an overall analysis of the efficacy of chronic disease self-management programs across conditions. This analysis is shown in Figure 24, which contains 47 comparisons from 33 studies. The overall pooled result is a statistically and clinically significant effect size favoring chronic disease self-management programs of -0.26; 95% CI: (-0.36, -0.15).

Figure 24. Forest Plot of Pooled Studies

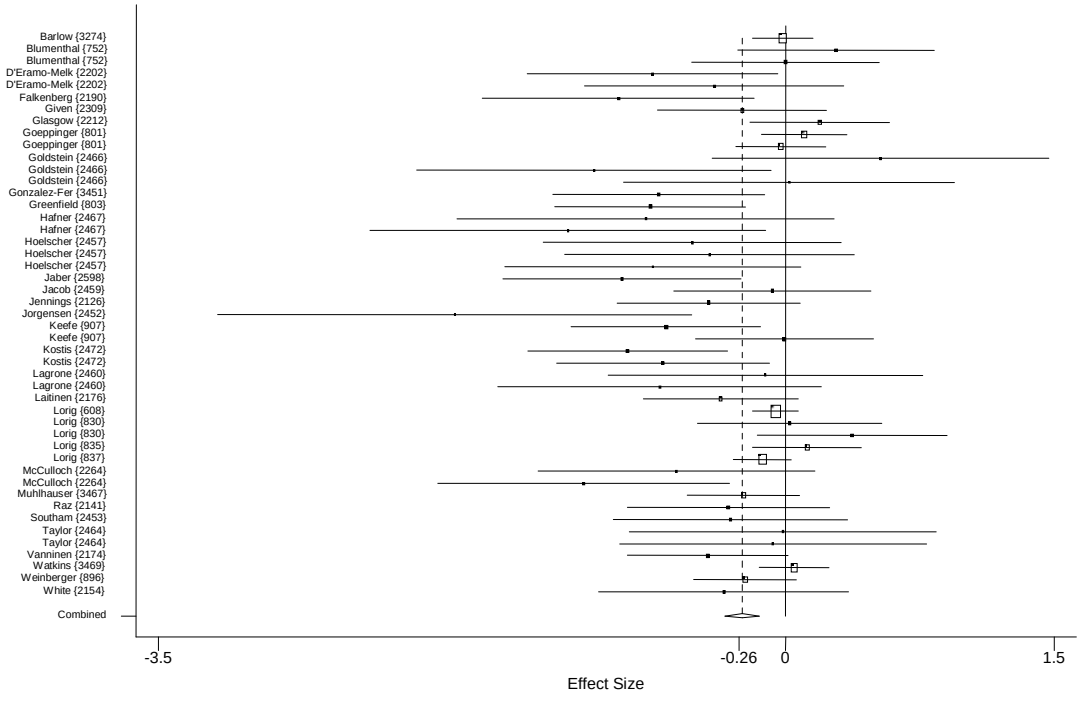
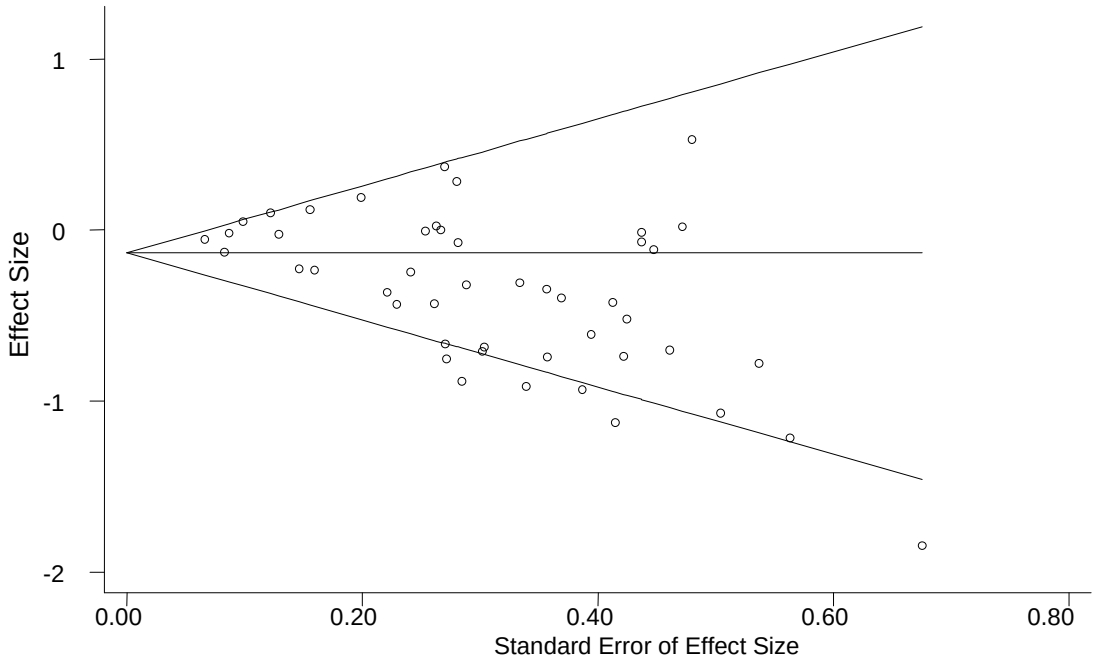


Figure 25. Funnel Plot of Pooled Studies



Tests of hypothesis of elements essential to chronic disease self-management efficacy

Tables 11 through 14 present the results of our analysis looking at the five hypotheses regarding the elements contributing to the effectiveness of chronic disease self-management programs. Other than the increased effectiveness seen in hypertension studies reporting systolic blood pressure outcomes that used tailored interventions, there were no statistically significant differences between interventions with or without the 5 features hypothesized to be related to effectiveness (tailoring, use of group setting, feedback, psychological component, and MD care). Indeed, many of the effects seen are inconsistent across outcomes within the same condition. For example, in hypertension studies, for hypothesis 2 (use of a group setting), there is a greater than 50% increase in the effect size for improvement in systolic blood pressure, but only a 5% increase in the effect size for improvement in diastolic blood pressure (note that neither result is

statistically significant). In other situations, the effect actually goes the opposite way (for example, hypothesis 4, the use of a psychological component, shows opposite effects in studies of diabetes depending on whether hemoglobin A1c or fasting blood glucose is used as the outcome).

Our "across condition" analysis, presented in Table 15 shows effect sizes that, in general, go in the direction of supporting increased effectiveness associated with the use of these intervention features, however none of the differences are statistically significant.

Table 11. Meta-Analysis Results for Diabetes

Outcome		Hemoglobin A1c (N = 12)		Weight (N = 8)		Fasting blood glucose (N = 9)	
		# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)
Overall		14	-0.45 (-0.63, -0.26)	10	-0.05 (-0.23, 0.12)	10	-0.41 (-0.60, -0.23)
Tailored	No	1	-0.32 (-1.05, 0.41)	1	0.0 (-0.56, 0.56)	1	-0.81 (-1.42, -0.20)
	Yes	13	-0.46 (-0.66, -0.26)	9	-0.06 (-0.24, 0.12)	9	-0.37 (-0.55, -0.19)
Group Setting	No	4	-0.50 (-0.83, -0.18)	2	-0.05 (-0.39, 0.30)	4	-0.38 (-0.68, -0.09)
	Yes	10	-0.42 (-0.66, -0.18)	8	-0.05 (-0.25, 0.15)	6	-0.46 (-0.74, -0.18)
Feedback	No	4	-0.26 (-0.58, 0.07)	3	0.10 (-0.18, 0.38)	2	-0.42 (-0.90, 0.06)
	Yes	10	-0.52 (-0.73, -0.30)	7	-0.15 (-0.38, 0.07)	8	-0.42 (-0.65, -0.20)
Psychological	No	8	-0.48 (-0.74, -0.22)	5	-0.09 (-0.36, 0.18)	5	-0.37 (-0.63, -0.11)
	Yes	6	-0.42 (-0.71, -0.12)	5	-0.02 (-0.25, 0.20)	5	-0.49 (-0.80, -0.18)
MD Care	No	13	-0.45 (-0.66, -0.25)	9	-0.04 (-0.22, 0.15)	8	-0.48 (-0.70, -0.27)
	Yes	1	-0.43 (-1.08, 0.21)	1	-0.14 (-0.59, 0.30)	2	-0.20 (-0.58, 0.18)
Overall Chi-squared p-value			0.081		0.942		0.195

N = number of studies contributing data; CI = confidence interval; NE = not estimable

Table 12. Meta-Analysis Results for Osteoarthritis

Outcome		Pain (N = 7)		Functioning (N = 7)	
		# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)
Overall		10	-0.04 (-0.11, 0.04)	10	-0.01 (-0.09, 0.07)
Tailored	No	0	NE	0	NE
	Yes	10	NE	10	NE
Group Setting	No	1	0.10 (-0.14, 0.34)	1	0.17 (-0.06, 0.41)
	Yes	9	-0.05 (-0.13, 0.02)	9	-0.03 (-0.11, 0.04)
Feedback	No	4	-0.04 (-0.17, 0.10)	4	0.01 (-0.13, 0.16)
	Yes	6	-0.04 (-0.12, 0.05)	6	-0.01 (-0.11, 0.08)
Psychological	No	3	0.04 (-0.13, 0.20)	3	0.10 (-0.07, 0.26)
	Yes	7	-0.05 (-0.14, 0.03)	7	-0.04 (-0.12, 0.04)
MD Care	No	10	NE	10	NE
	Yes	0	NE	0	NE
Overall Chi-squared p-value			0.243		0.532

N = number of studies contributing data; CI = confidence interval; NE = not estimable

Table 13. Meta-Analysis Results for Post-Myocardial Infarction Care

Outcome		Mortality (N = 9)		Return to Work (N = 8)	
		# comparisons	risk ratio (95% CI)	# comparisons	risk ratio (95% CI)
Overall		9	1.04 (0.56, 1.95)	10	1.02 (0.97, 1.08)
Tailored	No	0	NE	0	NE
	Yes	9	NE	10	NE
Group Setting	No	5	1.22 (0.54, 2.79)	4	1.02 (0.95, 1.11)
	Yes	6	0.81 (0.32, 2.05)	6	1.01 (0.92, 1.11)
Feedback	No	4	1.01 (0.34, 3.20)	4	0.91 (0.81, 1.02)
	Yes	6	1.03 (0.48, 2.23)	6	1.05* (1.00, 1.11)
Psychological	No	4	1.81 (0.68, 5.35)	4	0.97 (0.88, 1.07)
	Yes	7	0.69 (0.31, 1.54)	6	1.05 (0.98, 1.13)
MD Care	No	8	1.09 (0.57, 2.10)	9	1.01 (0.95, 1.08)
	Yes	1	0.52 (0.01, 9.90)	1	1.07 (0.94, 1.22)
Overall Chi-squared p-value			0.30		0.035

N = number of studies contributing data; CI = confidence interval; NE = not estimable
** "yes" is statistically significant as compared to "no" (p<0.05)*

Table 14. Meta-Analysis Results for Hypertension

Outcome		Systolic BP (N = 14)		Diastolic BP (N = 14)	
		# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)
Overall		23	-0.32 (-0.50, -0.15)	23	-0.59 (-0.81, -0.38)
Tailored	No	6	-0.08 (-0.33, 0.16)	6	-0.41 (-0.78, -0.03)
	Yes	17	-0.41* (-0.59, -0.22)	17	-0.67 (-0.92, -0.42)
Group Setting	No	10	-0.20 (-0.46, 0.06)	10	-0.54 (-0.87, -0.21)
	Yes	13	-0.41 (-0.65, -0.18)	13	-0.64 (-0.94, -0.35)
Feedback	No	13	-0.26 (-0.49, -0.02)	13	-0.56 (-0.85, -0.26)
	Yes	10	-0.40 (-0.67, -0.14)	10	-0.65 (-0.98, -0.32)
Psychological	No	8	-0.25 (-0.50, 0.00)	8	-0.44 (-0.76, -0.12)
	Yes	15	-0.38 (-0.62, -0.14)	15	-0.70 (-0.98, -0.42)
MD Care	No	23	NE	23	NE
	Yes	0	NE	0	NE
Overall Chi-squared p-value			0.008		0.000

N = number of studies contributing data; CI = confidence interval; NE = not estimable
** "yes" is statistically significant as compared to "no" (p<0.05)*

Table 15. Meta-Analysis Results Pooled Across Conditions

Outcome		Pain, Hemoglobin A1c, Systolic (N = 30) # comparisons	effect size (95% CI)	Adjusted effect size (95% CI)
Overall		47	-0.26 (-0.36, -0.15)	NA
Tailored	No	7	-0.14 (-0.42, 0.13)	NA
	Yes	40	-0.28 (-0.39, -0.16)	-0.21 (-0.53, 0.12)
Group Setting	No	15	-0.26 (-0.46, -0.07)	NA
	Yes	32	-0.26 (-0.38, -0.13)	-0.16 (-0.45, 0.14)
Feedback	No	21	-0.16 (-0.32, 0.00)	NA
	Yes	26	-0.32 (-0.46, -0.18)	-0.27 (-0.69, 0.15)
Psychological	No	19	-0.27 (-0.43, -0.11)	NA
	Yes	28	-0.25 (-0.39, -0.11)	-0.08 (-0.51, 0.34)
MD Care	No	46	-0.25 (-0.36, -0.15)	NA
	Yes	1	-0.43 (-1.09, 0.22)	-0.23 (-0.99, 0.54)
Overall Chi-squared p-value			0.000	NA

N = number of studies contributing data; CI = confidence interval; NE = not estimable
Adjusted effect size is adjusted for all components simultaneously

Post Hoc Analyses

Components of CDSM according to RE-AIM

The components of CDSM can be classified using RE-AIM as:

- one-on-one counseling interventions (individual)
- group sessions (group)
- telephone calls (telephone)
- interactive computer-mediated interventions (computer)
- mail interventions (mail)
- health system policies (policy 1 and policy 2)

The results of the meta-regression analyses are presented in Tables 16-20. With few exceptions, there were no results that were statistically significant. An exception is the result for the use of one-on-one counseling sessions, which did show a statistically significant increased effect size when used. "Policy 1" is the variable we constructed using a strict definition of health system policies, while "Policy 2" uses a broad definition of health system policies.

Table 16. Meta-Analysis Results for Diabetes (RE-AIM Model)

Outcome		Hemoglobin (N = 12)		Weight (N = 8)		Blood Glucose (N = 9)	
		# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)
Overall		14	-0.45 (-0.63, -0.26)	10	-0.05 (-0.23, 0.12)	10	-0.41 (-0.60, -0.23)
Individual	No	6	-0.23 (-0.44, -0.02)	3	0.0 (-0.29, 0.29)	3	-0.55 (-0.89, -0.20)
	Yes	8	-0.60* (-0.83, -0.38)	7	-0.08 (-0.30, 0.13)	7	-0.36 (-0.60, -0.11)
Group	No	6	-0.54 (-0.82, -0.27)	3	-0.05 (-0.36, 0.27)	4	-0.38 (-0.68, -0.09)
	Yes	8	-0.36 (-0.62, -0.10)	7	-0.05 (-0.26, 0.15)	6	-0.46 (-0.74, -0.18)
Telephone	No	13	-0.48 (-0.68, -0.28)	10	NE	9	-0.44 (-0.67, -0.22)
	Yes	1	-0.23 (-0.74, 0.29)	0	NE	1	-0.32 (-0.78, 0.13)
Computer	No	14	NE	10	NE	10	NE
	Yes	0	NE	0	NE	0	NE
Mail	No	14	NE	10	NE	10	NE
	Yes	0	NE	0	NE	0	NE
Policy 1	No	13	-0.48 (-0.68, -0.28)	10	NE	9	-0.44 (-0.67, -0.22)
	Yes	1	-0.23 (-0.74, 0.29)	0	NE	1	-0.32 (-0.78, 0.13)
Policy 2	No	13	-0.48 (-0.68, -0.28)	10	NE	9	-0.44 (-0.67, -0.22)
	Yes	1	-0.23 (-0.74, 0.29)	0	NE	1	-0.32 (-0.78, 0.13)
			0.081		0.942		0.195

N = number of studies contributing data; CI = confidence interval; NE = not estimable
** "yes" is statistically significant as compared to "no" (p<0.05)*

Table 17. Meta-Analysis Results for Osteoarthritis (RE-AIM Model)

Outcome		Pain (N = 7)		Functioning (N = 7)	
		# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)
Overall		10	-0.04 (-0.11, 0.04)	10	-0.01 (-0.09, 0.07)
Individual	No	10	NE	10	NE
	Yes	0	NE	0	NE
Group	No	1	-0.67 (-1.20, -0.14)	1	0.06 (-0.46, 0.59)
	Yes	9	-0.02* (-0.10, 0.05)	9	-0.01 (-0.09, 0.08)
Telephone	No	8	-0.03 (-0.10, 0.05)	8	-0.01 (-0.10, 0.07)
	Yes	2	-0.32 (-0.68, 0.05)	2	0.17 (-0.20, 0.53)
Computer	No	10	NE	10	NE
	Yes	0	NE	0	NE
Mail	No	9	-0.05 (-0.13, 0.02)	9	-0.03 (-0.11, 0.04)
	Yes	1	0.10 (-0.14, 0.34)	1	0.17 (-0.06, 0.41)
Policy 1	No	9	-0.03 (-0.12, 0.06)	9	0.03 (-0.05, 0.12)
	Yes	1	-0.06 (-0.19, 0.07)	1	-0.12* (-0.25, 0.01)
Policy 2	No	9	-0.03 (-0.12, 0.06)	9	0.03 (-0.05, 0.12)
	Yes	1	-0.06 (-0.19, 0.07)	1	-0.12* (-0.25, 0.01)
Chi-squared p-value			0.243		0.532

N = number of studies contributing data; CI = confidence interval; NE = not estimable
** "yes" is statistically significant as compared to "no" (p<0.05)*

Table 18. Meta-Analysis Results for Post-Myocardial Infarction Care (RE-AIM Model)

Outcome		Return to Work (N = 8)	
		# comparisons	risk ratio (95% CI)
Overall		10	1.02 (0.97, 1.08)
Individual	No	5	0.97 (0.89, 1.06)
	Yes	5	1.05 (1.00, 1.11)
Group	No	5	1.03 (0.95, 1.11)
	Yes	5	1.01 (0.92, 1.11)
Telephone	No	9	1.00 (0.95, 1.08)
	Yes	1	1.07 (0.94, 1.22)
Computer	No	10	NE
	Yes	0	NE
Mail	No	7	1.03 (0.95, 1.11)
	Yes	3	1.01 (0.92, 1.11)
Policy 1	No	10	NE
	Yes	0	NE
Policy 2	No	10	NE
	Yes	0	NE
Chi-squared p-value			0.035

N = number of studies contributing data; CI = confidence interval; NE = not estimable
NA = not applicable
Note: it was not possible to perform this analysis for the outcome "mortality".

Table 19. Meta-Analysis Results for Hypertension (RE-AIM Model)

Outcome		Systolic BP (N = 14)		Diastolic BP (N = 14)	
		# comparisons	effect size (95% CI)	# comparisons	effect size (95% CI)
Overall		23	-0.32 (-0.50, -0.15)	23	-0.59 (-0.81, -0.38)
Individual	No	17	-0.32 (-0.53, -0.12)	17	-0.64 (-0.79, -0.30)
	Yes	6	-0.33 (-0.70, 0.05)	6	-0.75 (-1.19, -0.31)
Group	No	15	-0.21 (-0.42, -0.01)	15	-0.51 (-0.78, -0.24)
	Yes	8	-0.48 (-0.76, -0.21)	8	-0.75 (-1.12, -0.38)
Telephone	No	22	-0.32 (-0.50, -0.14)	22	-0.57 (-0.79, -0.35)
	Yes	1	-0.42 (-1.39, 0.54)	1	-1.24 (-2.38, -0.10)
Computer	No	23	NE	23	NE
	Yes	0	NE	0	NE
Mail	No	23	NE	23	NE
	Yes	0	NE	0	NE
Policy 1	No	20	-0.40 (-0.55, -0.17)	20	-0.63 (-0.86, -0.39)
	Yes	3	-0.06 (-0.57, 0.46)	3	-0.38 (-0.99, 0.24)
Policy 2	No	20	-0.40 (-0.55, -0.17)	20	-0.63 (-0.86, -0.39)
	Yes	3	-0.06 (-0.57, 0.46)	3	-0.38 (-0.99, 0.24)
Chi-squared p-value			0.008		0.006

N = number of studies contributing data; CI = confidence interval; NE = not estimable

Table 20. Meta-Analysis Results Pooled Across Conditions (RE-AIM Model)

Outcome		Pain, Hemoglobin A1c, Systolic (N = 30)		Adjusted
		# comparisons	effect size	effect size
Overall		47	-0.26 (-0.36, -0.15)	NE
Individual	No	33	-0.14 (-0.23, -0.05)	NE
	Yes	14	-0.51* (-0.70, -0.32)	-0.54* (-0.75, -0.34)
Group	No	22	-0.35 (-0.51, -0.19)	NE
	Yes	25	-0.18 (-0.31, -0.05)	-0.15 (-0.26, -0.03)
Telephone	No	43	-0.25 (-0.37, -0.14)	NE
	Yes	4	-0.30 (-0.65, 0.04)	-0.34 (-0.65, -0.04)
Computer	No	47	NE	NE
	Yes	0	NE	NE
Mail	No	46	-0.27 (-0.37, -0.16)	NE
	Yes	1	0.10 (-0.41, 0.61)	0.03 (-0.39, 0.45)
Policy 1	No	42	-0.28 (-0.39, -0.17)	NE
	Yes	5	-0.10 (-0.40, 0.20)	-0.07 (-0.35, 0.20)
Policy 2	No	42	-0.28 (-0.39, -0.17)	excluded from model
	Yes	5	-0.10 (-0.40, 0.20)	
Chi-squared p-value			0.000	

N = number of studies contributing data; CI = confidence interval; NE = not estimable
** "yes" is statistically significant as compared to "no" (p<0.05)*
Adjusted effect size is adjusted for all components simultaneously

Effectiveness of CDSM According to Baseline Severity

We were able to perform the meta-analysis according to baseline severity for hemoglobin A1c and weight outcomes in diabetes, and pain and function for osteoarthritis. For hemoglobin A1c, a study's sample was considered more severe if the mean baseline hemoglobin value was greater than or equal to 10%. Seven out of the 12 studies were considered more severe, which provided 9 comparisons. For weight, severity was assigned to studies with a mean baseline weight of greater than 185 lbs or 84.1 kgs, or BMI greater than 30 kg/m2. Six of the 8 weight studies were categorized as "more severe" which provided seven comparisons. For the pain outcome, a study had a more severe patient sample if the mean baseline pain value was greater than 5 on a 0-10 or 0-15 Visual Analogue Scale or on the AIMs pain scale. Four of the six pain studies were rated as "more severe" which provided 6 comparisons. A sample was considered more severe for the functioning outcome if the baseline mean was greater than one on the HAQ (0-3). One of the six studies was considered "more severe" which provided one comparison. Effect sizes were then compared between studies of "more severe" and "less severe" patients at baseline. Only the assessment of hemoglobin A1c demonstrated an increased effect size in patients who were more severely effected, and this difference did not quite reach conventional levels of statistical significance.

Table 21. Meta-analysis Results for Diabetes (Severity Model)

Level	Hemoglobin A1c (N = 12) # comparisons	Hemoglobin A1c (N = 12) effect size (95% CI)	Weight (N = 8) # comparisons	Weight (N = 8) effect size (95% CI)
More Severe	9	-0.55 (-0.79, -0.31)	7	-0.04 (-0.42, 0.35)
Less Severe	5	-0.29 (-0.57, -0.01)	3	-0.06 (-0.25, 0.14)

N = number of studies contributing data; CI = confidence interval; NE = not estimable

Table 22. Meta-analysis Results for Osteoarthritis (Severity Model)

Level	Pain (N = 6) # comparisons	Pain (N = 6) effect size (95% CI)	Functioning (N = 6) # comparisons	Functioning (N = 6) effect size (95% CI)
More Severe	6	-0.04 (-0.14, 0.05)	1	-0.02 (-0.11, 0.08)
Less Severe	4	-0.03 (-0.14, 0.08)	9	0 (-0.20, 0.20)

N = number of studies contributing data; CI = confidence interval

Effectiveness of CDSM Program Components According to the "Essential Elements of Self-management Interventions"

For the "Essential Elements of Self-management Interventions" evaluation, we did not find as much variation among studies and components as is necessary for optimal power in the analysis. Most of the studies scored positively for "problem identification and solving," and did not score positively for the "ensuring implementation component." Given these data, we did not find evidence to support either any one of these three broad "essential elements" as necessary, nor some threshold (such as two out of three) in terms of efficacy. This was not an optimal test of these hypotheses due to the lack of variation in the data.

Table 23. Meta-analysis Results Pooled Across Conditions ("Essential Elements" Model)

Outcome		Pain, Hemoglobin A1c, Systolic (N = 30)		Adjusted
		# comparisons	effect size	effect size
Problem	No	8	-0.24 (-0.47, 0)	NE
	Yes	39	-0.26 (-0.38, -0.14)	-0.27 (-0.46, -0.09)
Support	No	28	-0.27 (-0.41, -0.13)	NE
	Yes	19	-0.24 (-0.41, -0.08)	-0.20 (-0.54, 0.14)
Track	No	44	-0.25 (-0.35, -0.14)	NE
	Yes	3	-0.38 (-0.76, 0.01)	-0.35 (-0.84, 0.13)

N = number of studies contributing data; CI = confidence interval; NE = not estimable
Adjusted effect size is adjusted for all three components simultaneously

Effectiveness According to Intermediate Variables

Figures 26 and 27 present graphical representations of the correlation between "intermediate" variable 1 and variable 2, and between variable 2 and outcome. Figure 26 shows that the correlation between intermediate variables 1 and 2 is strongly effected by outliers. Including two outlier values actually produces a negative correlation, meaning that improvements in intermediate variable 1 (such as self-efficacy, patient knowledge, and psychological measures) actually is associated with worsening values for intermediate 2 variables (such as dietary measures, physical activity, and behavioral measures). Ignoring the two outlier values yields a correlation in the expected direction. Figure 27 shows that the correlation of intermediate 2 on outcome is weak but in the expected direction.

Figure 26. Regression of Intermediate 2 on Intermediate 1

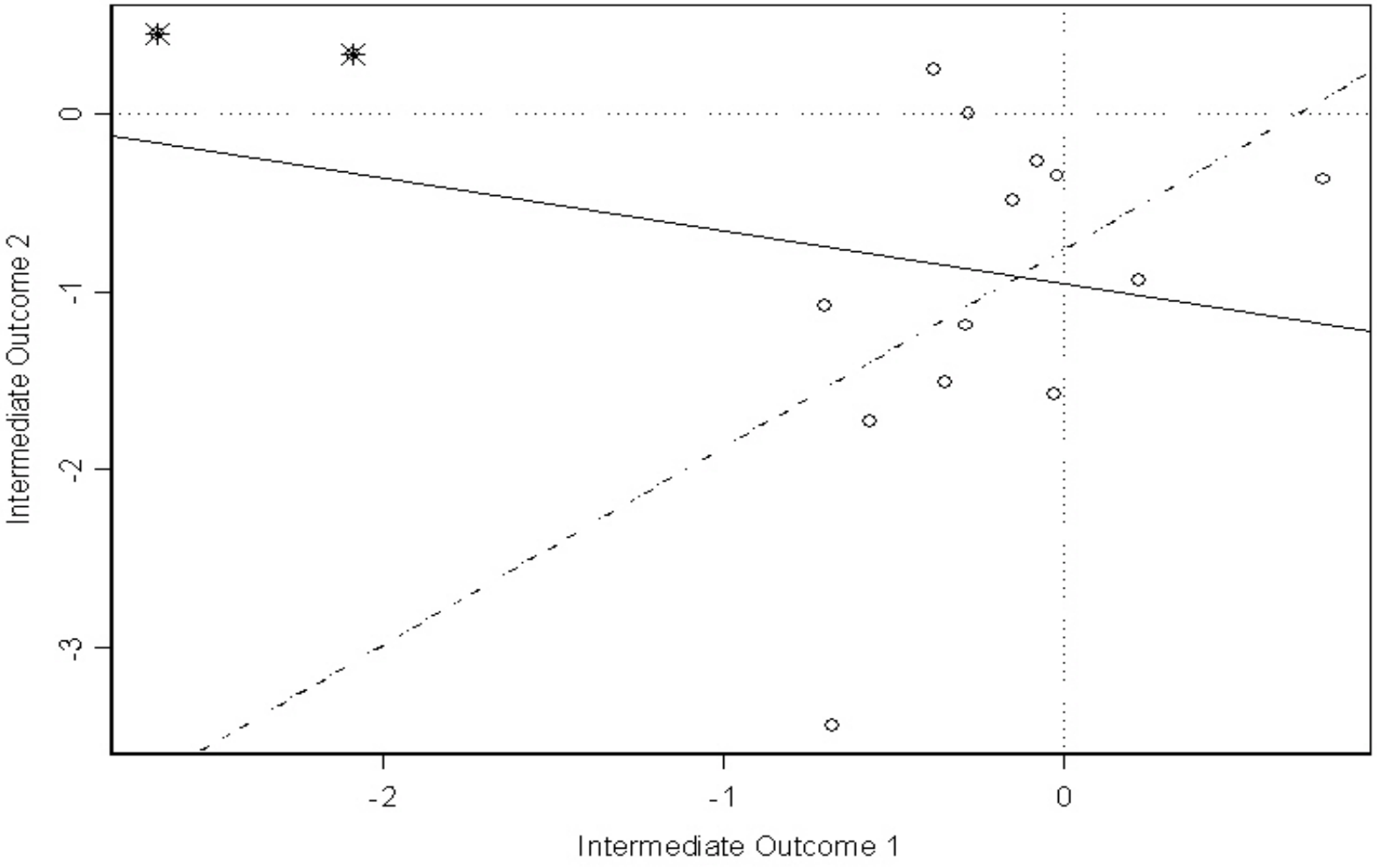
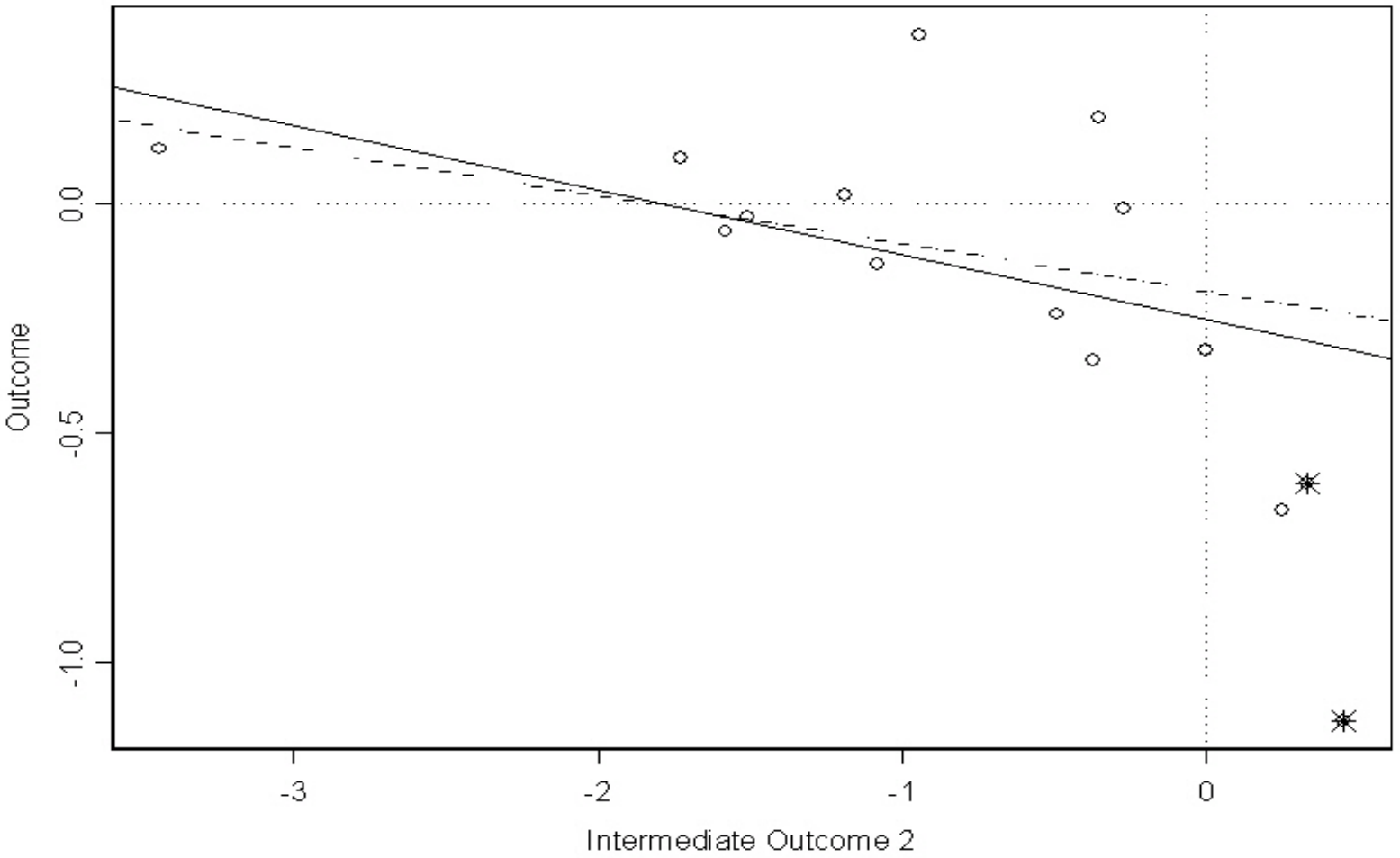


Figure 27. Regression of Outcome on Intermediate 2



Question 3. Does this intervention belong in the medical care system?

Whether chronic disease self-management belongs in the medical care system or in the community is a decision that needs to be made by policy makers, based on many factors. That being said, one of the first hypotheses we tested was whether patients who receive interventions directly from their medical providers are more likely to have better outcomes than those who received interventions from non-medical providers. Of the controlled studies that made it into our meta-analysis, no studies of osteoarthritis or hypertension used medical providers in their self-management interventions. Regarding diabetes, one intervention used medical providers; the results of this intervention were not significantly different than those using lay leaders (see Table 11). One post-myocardial infarction intervention used medical providers; the effects on mortality and return to work were not statistically different from those of the other interventions.

Question 4. Define chronic disease self-management and distinguish between it and disease management.

There is no standard definition of chronic disease self-management. For purposes of this review, we initially defined chronic disease self-management broadly as a systematic intervention that is targeted towards patients with chronic disease to help them to actively participate in either or both of the following activities: self monitoring (of symptoms or physiologic processes) or decision-making (managing the disease or its impact based on self-monitoring). Our analytic attempts to "define" chronic disease self-management by identifying the components most responsible for the success of the program were unsuccessful.

The draft evidence report was presented to a group of experts in chronic disease self-management at a meeting convened by the Robert Wood Johnson Foundation and held in Seattle

on December 14, 2001. The list of experts attending is present in Appendix A. The panel's aim was to focus on interventions offered to patients who need a more intense level and type of self-management support. They agreed that all self-management programs should address the following three areas.

Disease, medication, and health management. While patients need medical information about their particular disease (diabetes, arthritis, asthmas, etc.), the majority of the content in most successful self-management programs emphasized generic lifestyle issues such as exercise, nutrition, and coping skills. More disease-specific medication-specific information can be useful, but such information rarely constitutes more than 20 percent of the content of programs.

Role management. Patients benefit from programs that help them maintain social support, connection to work and family, and normal functions of daily life.

Emotional management. Programs should encompass managing depression and stress, adaptation to change, and maintaining interpersonal relationships.

A monograph authored by Dr. Jesse Gruman (Center for the Advancement of Health, 2002) summarized the discussions from the meeting of December 14, 2001. The experts concluded that the essential elements of self-management programs should include the following:

1. Problem-solving training that encourages patients and providers to identify problems, identify barriers and supports, generate solutions, form an individually tailored action plan, monitor and assess progress toward goals, and adjust the action plan as needed.

2. Follow-up to maintain contact and continued problem-solving support, to identify patients who are not doing well and assist them in modifying their plan, and to relate the plan to the patient's social/ cultural environment.

3. Tracking and ensuring implementation by linking the program to the patient's regular source of medical care and by monitoring the effects of the program on the patient's health, satisfaction, quality of life, and health system quality measures.

The experts also recommended that any chronic disease self-management program be composed of two tiers to accommodate the wide variety of patients with chronic conditions. The first tier would include a low-intensity intervention designed to reach mass audiences and open to anybody with a particular illness. The second tier would include a high-intensity intervention targeted to people who require one-on-one support and case management. This program could be offered to those who have not successfully managed their condition with the minimal support of tier #1, those who have complicated conditions, and those whose life circumstances or conditions change significantly.

Question 5. What is the role or potential of technology?

The advent of new technologies makes communication between patients, providers, and others more convenient than ever. However, none of the randomized controlled studies on chronic disease self-management used email or the Internet. Thus, we were not able to quantitatively assess the impact of these technologies. Still, incorporating these technologies into future randomized studies would be a worthwhile endeavor.

None of the randomized controlled trials of programs for arthritis, hypertension, or post-myocardial infarction involved patient use of computer programs. However, diabetes self-

management programs have utilized computer programs since the late 1970s. Randomized controlled trials are discussed below.

The DIABEDS study, conducted from 1978 to 1982 at University of Indiana, used computers to generate diet menus and physician reminders.[35, 36] Over 500 patients were assigned to either routine care, patient education, physician education, or both physician and patient education. At two-year follow-up, the combination of patient plus physician education resulted in the greatest improvements in fasting plasma glucose, hemoglobin A1C, body weight, and diastolic blood pressure. A small substudy was conducted at the university on computer-based techniques for diet education and meal planning.[37] Sixteen inner city, low SES patients received computer-assisted instruction combined with an interactive videodisc system. They also received face-to-face education from a dietitian. The computer –assisted instruction was operated entirely by the patient, who answered questions by pressing on of three color-coded keys on the keyboard. At four-week follow-up the group had lost an average of 4.6 pounds ($p<0.005$) and reduced their reported fat intake ($p<0.05$).

Scientists in the U.K. also designed and evaluated two interactive computer based diabetes education tools in the early 1980s.[38] One was a teaching program with animated graphics, while the other was a multiple choice knowledge assessment with optional prescriptive feedback. Each program used questioning after each provision of fact, followed by optional or compulsory rerun of the fact sequence if inadequate performance was recorded. Patients could progress through the programs at their own rate. In a controlled trial, the programs led to an increase in knowledge and a decrease in Hemoglobin A1c levels.

More recently, Glasgow and colleagues developed a single session MD office-based intervention for diabetics using a brief touchscreen computer assessment that provided

individualized feedback to both providers and patients.[39] The feedback took the form of a report on key barriers to dietary self-management, along with goal setting and problem-solving counseling. At three-month follow-up, intervention patients had lowered mean serum cholesterol from 216 to 207, while patients in the usual care group actually increased total cholesterol from 223 to 231 ($p<0.001$). In addition, intervention patients had larger decreases in percent of calories from fat ($p<0.008$). Differences remained significant at twelve months.[40]

Recently, Lorig and colleagues reported the results of an "email discussion group" for patients with back pain.[41] While not one of our conditions of interest, and also not assessing older individuals (mean age of study subjects was 45 years), the results are the first we have found to assess the use of internet technology in patient management of a chronic illness. The "email discussion group" participants received an educational book and videotape about back pain, and had access to an email listserve where subjects could post questions or comments about their illness. The "email discussion group" was moderated by content experts who answered (non-participant specific) questions about back pain. The authors report that at one year subjects in the "email discussion group" had, compared to controls that received a magazine subscription, modest improvements in measures of self-efficacy, self-care orientation, pain interference, and health related quality of life, and about one less physician visit for back pain over the past year. This study suggests that email and the Internet may be a promising method for delivering self-care interventions.

Question 7. To what extent does self-management educate a patient on how to care for himself/herself (e.g., take medications appropriately, consult with a physician when necessary, etc.)?

Most CDSM studies that assess knowledge and self-efficacy reported beneficial improvements. Most studies did NOT measure whether medications were taken appropriately or "necessary" physician visits were made. The two studies that did assess compliance were hypertension studies. One had a borderline beneficial overall result; the other reported a significant beneficial result. One study was based on a conceptual model that specifically considered that changing medication-taking behavior was going to be easier than changing diet behavior or other such behaviors. This study did not actually measure compliance, but rather measured "commitment to taking medications" and showed that this differed between intervention and controls and that it was one of only three variables among those tested to be associated with significant changes in blood pressure (the other two were ""belief in severity of the disease" and "beliefs in efficacy of therapy"). Many studies assessed utilization, but none assessed whether the utilization was necessary.

Question 8. What is the patient's retention of self-management skills after the intervention? Is a follow-up intervention needed at some point?

The best way to answer this question would be to review clinical trials where one arm receives a "follow-up intervention" and another does not. No such studies were found. Failing this, we could compare the results of studies that included a "follow-up intervention" with studies that did not. Again, we were unable to find studies that actually included a "follow-up intervention" which incorporated refresher skills on self-management. In light of this, we used a meta-regression model to test whether self-management interventions that provide follow-up

support led to better results than those that did not. We classified interventions that maintained contact with the patient through contracts, provider feedback, reminders, peer support, material incentives, or home visits as including "follow-up support." Of the interventions which could be included in our meta-analyses, 19 had "follow-up support" while 28 did not. Pooled results were not statistically different between the two groups.

Question 9. How does the approach for self-management differ for people with multiple chronic diseases?

We found no evidence on this topic.

Question 11. Should this intervention be targeted to a subset of the population or available to everyone? Are there particular chronic conditions that should be addressed (e.g., diabetes, arthritis, stroke, cancer, Parkinson's, hypertension, dyslipidemia)?

We were able to quantitatively assess the effects of chronic disease self-management programs on patients with diabetes, osteoarthritis, and hypertension. In addition, we were able to pool results for post myocardial infarction programs. There were insufficient studies on stroke, cancer, Parkinson's and dyslipedemia to allow pooling. As reported above, self-management programs for hypertension had a significant beneficial effect on systolic and diastolic blood pressure when compared to usual care. Programs for diabetics showed a beneficial effect on hemoglobin A1c and blood glucose, but not on weight. There was insufficient evidence to support a beneficial effect on the health outcomes for pain and function for programs targeting patients with osteoarthritis or the health outcomes of death or return-to-work for heart attack patients.

In an attempt to assess whether chronic disease self-management programs were more effective for more severe patients, we undertook a post-hoc quantitative analysis. Two clinicians independently categorized each diabetes and osteoarthritis program as focusing on either more severe or less severe patients. The clinicians were unable to categorize the hypertension and post- MI programs in such a fashion, due to the lack of heterogeneity of the patients. In the diabetes analysis, there was no statistical difference between the effectiveness of programs targeted to more severe and less severe patients, in terms of change in hemoglobin A1c or weight. For osteoarthritis studies, there was no statistical difference in change in pain or functioning.

Question 12. What is the role of the physician? Can physicians be used to reinforce learning?

Out meta-analysis did not reveal any statistically significant differences supporting the role of physicians at enhancing the efficacy of chronic disease self-management programs.

Question 13. Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?

A total of 19 clinical trial studies were identified in this review of the economic impact of Chronic Disease Self-Management (CDSM). These include 9 studies on diabetes, 4 studies on osteoarthritis, one study on hypertension, two on post-myocardial infarction, and three non-disease-specific programs for chronically ill patients.

The 19 articles were located by four search methods: 1) previously described Quality Review Form (QRF) with the key words “cost” or “utilization,” 2) references listed in relevant

articles or review articles (e.g., Clement,[42] Norris,[43] Klonoff[44]), 3) key word "health care use/costs" search in "An Indexed Bibliography on Self-Management for People with Chronic Disease," and 4) a PubMed search with key words "diabetes," "osteoarthritis," "hypertension," "self-care," and "cost," "cost-effectiveness" or "economics." Then we did title and abstract screening to choose the literature. Finally, after careful assessment of study quality and relevance for CDSM and economic analysis, 19 studies representing 19 programs were selected for review (Evidence Table 5). All studies were randomized clinical trials if not otherwise indicated.

Diabetes

The type of articles included in our economic review of diabetic self-management programs discuss:

1. Providing patient education programs,[45-47]
2. Comparing relative effectiveness of various intensity of educational programs,[48, 49]
3. Providing behavioral-based interventions,[50]
4. Providing dietary-specific interventions,[40] and
5. Providing CDSM education and support as part of changes in the healthcare delivery system.[51, 52]

Two of the three educational programs[45, 47] failed to demonstrate effectiveness for the measured outcomes. Thus these interventions cannot be cost-effective. The hospital education program in de Weerdt[47] incurred program costs – direct and indirect – at US $144 (1990 dollars,

about $240 in 2002 dollars[*]) per participant. The home visitation education program in Rettig[45] was more expensive with an estimated program cost at $175 per participant (1983 dollars, about $470 in 2002 dollars). Authors of both studies attribute the ineffectiveness of the interventions partially to lack of supportive changes in the healthcare delivery system.

Wood[46] reported that hospitalized patients who received an inpatient group education program, which stressed both knowledge and self-help behaviors, experienced a significantly lower emergency room (ER) visitation rate over the next four months ($p < 0.005$). Based on self-report, the 40 control patients reported 20 ER visits, and the 53 intervention patients reported only two ER visits. Moreover, the control patients reported 18 hospital readmissions, whereas the intervention patients reported only eight hospital readmissions. Although program cost was not reported, the dramatic results in healthcare utilization outcomes would likely offset the program cost and result in cost savings.

Klonoff and Schwartz[44] conducted an economic analysis of interventions for diabetes, including a section on self-management programs. Of the six self-care education programs they analyzed, two were overlapped with the current review[45, 47] and were discussed above. These were the only two that did not report favorable cost-benefit results. The other four programs reported in six studies had a benefit-cost ratio ranging from $0.43 to $8.76 for each dollar spent.[53-58] However, all these programs were conducted in or before 1985.

Two studies compared the relative effectiveness of various intensities of educational programs.[48, 49] Arsennau[48] compared individualized learning activity packages (LAP) with

[*] The inflation to 2002 dollars is derived from the percentage increase from 1990 to 2002 in the Consumer Price Indexes of Total Medical Care Prices (From Statistical Abstract of United States, 2001). The indexes give 1990 = 162.8 given 1982-1984 = 100.

classroom instruction. LAP could provide a cheaper means of education for individuals by saving $108.50 (1994 dollars, about $140 in 2002 dollars) in instructional fees. However, the study reported LAP was less effective in lowering blood glucose levels than classroom education, and thus was likely not to save healthcare costs. Campbell[49] compared four programs ranging from minimal instruction to an intensive educational and behavioral program. They found that programs that were more intensive in terms of patient time and resources may be more effective, but became less cost-effective. Their results showed that the four programs of differing intensity had no difference in results in healthcare utilization and many outcome measures, except for that the most intensive program (behavioral program) did have greater reduction in diastolic blood pressure and cholesterol risk ratio along with higher patient satisfaction.

Kaplan and colleagues investigated behavioral-based interventions.[50] The authors reported direct costs for a program combining diet and exercise to be $1,000 (1986 dollars, about $2190 in 2002 dollars) per participant, and this program could result in 0.092 incremental years of well-being for each participant. The authors calculated the cost/utility equal to $10,870 (about $23,800 in 2002 value) per "well-year" by the combined program. A cost/utility ratio less than $50,000 is often considered cost-effective. Moreover, had the authors subtracted the cost of the control program (10 weeks of group education) from the cost of the intervention program ($1,000), the cost/utility ratio would have been even more favorable than the one they reported.

Glasgow[40] reported on a personalized, medical office-based intervention focused on behavioral issues related to dietary self-management. This intervention used touchscreen

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We assume the same rate of increase to estimate the index for 2002 to be 270. This method of inflation to 2002 dollars is applied to the rest of the cost data in this section of the report.

computer assessments to provide immediate feedback on key issues to patients and providers just prior to a visit, and provided goal setting and problem-solving assistance to patients following the visit with a physician. Follow-up components included phone calls and videotape or interactive video instruction depending on patient self-efficacy level. Incremental costs for the delivery of this intervention totaled $14,755 (1995 dollars, about $18065 in 2002 dollars), or $137 ($168 in 2002 dollars) per participant. At 12 month follow-up, this study resulted in $62 ($76 in 2002 dollars) per reduction of each percent in dietary fat, $105 ($129 in 2002 dollars) per percent reduction in saturated fat, and $8 ($10 in 2002 dollars) per mg/dl reduction in serum cholesterol. The authors reported these costs are quite low compared to other studies of pharmacological interventions to reduce cholesterol, which can cost from $350 ($430 in 2002 dollars) to $1,400 ($1715 in 2002 dollars) per patient per year. There were also significant differences favoring the intervention as measured by patient satisfaction ($p < 0.02$). However, there were no significant differences between groups to either hemoglobin A1c or on Body Mass Index.

There are many ways to provide CDSM education and support as part of changes in the healthcare delivery system. We were only able to review the economic impact of this type of intervention based on two studies.[51, 52] Sadur[51] reported that, for patients who had poor diabetic management, providing intensive multidisciplinary outpatient diabetes care management may be cost neutral in the short term. This could be achieved by significant improvement in glycemic control, which led to an early reduction in health care utilization, which would offset costs of the intervention promptly. However, it is too early to conclude if improved glycemic control really reduces health care utilization. Moreover, although the study reported the resources in terms of providers' time used for the program, the authors did not report the dollar figure that how much

the program costs. A cost-effectiveness study and replication of this intervention should be conducted.

Litzelman[52] investigated a multifaceted intervention that included patient education and a behavioral contract about foot-care, and provided patient reinforcement reminders. Other components of the intervention involved health care system support of identifiers on patient folders to prompt providers for foot-care, and giving providers practice guidelines and informational flow sheets on foot-related risk factors for amputation. This intervention resulted in improved foot-care outcomes and process measures. The authors reported this intervention would only cost $5,000 (1993 dollars, about $6700 in 2002 dollars) for study materials if it could be implemented with the existing staff of a healthcare organization.

Osteoarthritis

The four OA studies include three types of articles:

1. Comparing relative effectiveness of lay-taught and professional-taught educational programs,[59]
2. Providing patient education programs,[60, 61] and
3. Providing social support and education interventions.[62]

The study that compared lay-taught and professional-taught self-management courses reported that lay leaders could teach arthritis courses with results similar to those achieved by professionals.[59] Cost then became an issue of concern to patients and providers. The authors assumed that lay leaders would either volunteer their time or would be paid a maximum of $100 (1985 dollars, about $245 in 2002 dollars) for leading the course. Thus, the arthritis course that needed two lay-leaders would cost $0 to $200. On the other hand, a profession-led course would

cost $240 to $600. The authors reported, with similar effects, a lay-led course could result in savings of $40 to $600 per course over the same courses taught by health professionals. This cost savings, however, did not take into account any costs required for training and support of the lay leaders (such as a center to answer lay-leaders' questions). When compared with the no intervention group at four-month follow-up, we also note that this study failed to show any benefit in reducing the number of physician visits by either lay- or professional-led self-management courses.

A similar self-help education program for arthritis patients[60] was taught solely by lay persons in a four-month RCT with a 20-month follow-up.[†] At four months, arthritis patients who received the self-management course significantly exceeded control patients (who received no CDSM course) in knowledge, recommended behaviors, and in decreased pain. The number of visits to physicians was reduced without reaching statistical significance. The 20-month longitudinal data showed the number of physician visits reduced from baseline to four-month follow-up, and from four-months to eight-months, and remained about the same from eight-month to 20-months. However, none of the differences reached statistical significance.

In contrast to the previous two community-based educational programs, a more recent study,[61] a nonrandomized clinical trial, tested the effects of a limited self-care intervention for patients with knee OA that was delivered by an arthritis nurse specialist as an adjunct to primary care. This intervention emphasized nonpharmacologic management of joint pain and preservation of function by problem solving and by practicing behavioral principles of joint protection. Telephone follow-up at one week and one month after initial instruction was

designed as part of the intervention, and a full written report of patient teaching and outcomes as well as any needs or questions was placed in patient's clinic record for any action deemed necessary by the primary care physician. The results showed fewer physician visits by intervention subjects (median visits five) compared to attention-control subjects (median visits six)($p < 0.05$) at 1-year follow-up. Fewer visits translated directly into reduced clinic costs in the intervention group (median costs at 1996 dollars = $229/patient, about $270/patient in 2002 dollars), compared to controls (median costs = $305/patient, about $360/patient in 2002 dollars)($p < 0.05$). However, the intervention had no significant effects on utilization and costs of outpatient pharmacy, laboratory, or radiology services at the one-year follow-up. The authors reported 80% of the cost of delivering the intervention ($58.70 per participant at 1996 dollars, about $70 in 2002 dollars) was offset within one year by the reduced frequency and costs of primary care visits in this study.

Groessl and Cronan[62] in a recent study demonstrated that the monetary savings of a community-based social support and education intervention greatly outweighed the cost of conducting the intervention. In this study, 363 members of a health maintenance organization (HMO), 60 years of age and older with osteoarthritis were randomly assigned to one of three intervention groups (social support, education, or a combination of both) or to a control group. These intervention programs were adapted from existing efficacy programs.[61, 63-68] The total costs to deliver the intervention were $9,450 for social support group (1992 dollars, about $13,530 in 2002 dollars), $18,675 ($26,740 in 2002 dollars) for education group, and $14,175 ($20,300 in 2002 dollars) for combination group, totaling $42,300 ($60,580 in 2002 dollars).

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† The 20-month follow-up after the four months RCT was a longitudinal study design. In other words, only intervention subjects were followed up to 20 months whereas the control subjects were only followed up to 4 months.

After determining that there were no significant differences among the four groups when analyzed separately, the authors examined a planned comparison of differential changes in health care costs for the three intervention groups combined, in contrast to the control group. Assessed by patients' medical records, the results showed health care costs (all costs except for mental health services) increased less in the intervention groups than in the control group over the three year follow-up period. Health care cost savings were $1,156/participant (between $1,550 to $1,655 per participant in 2002 value) for year one and two, and $1,279/participant ($1,635/particpant in 2002 value) for year three. With 273 patients who remained in the study and completed the assessment, the one-year cost savings was $315, 588 ($451,955 in 2002 dollars), and resulted in a cost-benefit ratio of $315,588/$42,300 = $7.46:1. After discounting the savings at a rate of 5% per year, the total three-year cost-benefit ratio was calculated as $315,588 + $300,560 + $316,705 = $932,853/$42,300 = $22.05:1. The authors conducted sensitivity analysis and reported the cost-savings were quite robust.

There are three concerns in this study by Groessl and Cronan.[62] First is attrition. The authors found that the mean annual health care costs of participants who dropped out ($4,793 in 1992 dollars, about $6,865 in 2002 dollars) were significantly higher than those of participants who continued ($1,802 in 1992 dollars, about $2,580 in 2002 dollars). Secondly, health care costs did not vary as a function of attendance at the meetings. The authors argued that many of the study participants may have already been well educated about osteoarthritis and self-management principles and/or had strong support networks. This suggests that a shorter intervention, less than 20 meetings, might be just as effective. The last issue is about generalizability of the study to minority population; the sample was largely Caucasian (92.3%) with a mean age of 70 years old at entry into the study.

Among the four OA self-management studies reviewed, two of them reported significant reduction in healthcare utilization and costs.[61, 62] Of these two, one was an RCT[62] and the other design was non-randomized attention-control.[61] One RCT followed with a longitudinal study[60] reported a reduction in number of visits to physician, but did not reach statistical significance at $\alpha = 0.05$ level. The other study did not find reduction in number of physician visits, but showed a cheaper alternative – led by lay leaders – to deliver patient education with same effectiveness as a professional-led course.

Hypertension

For hypertension self-management, we identified only one study with economic information.[69, 70] This study was intended to investigate methods to enhance patient compliance with assigned relaxation practice and to understand the impact of accomplished relaxation on elevated blood pressure. Although all interventions were found to have significant effects on reducing blood pressure, the authors reported that group relaxation alone was the most cost-effective strategy as compared to individual training and group plus contingency contracting. This is because it achieved higher relaxation practice compliance and greater reductions in blood pressure while using the least time of the therapist. The authors did not provide the actual costs for therapist time; nor did they attempt to measure impact on healthcare costs or utilization. Thus we cannot judge if such a relaxation practice is cost saving.

Post-Myocardial Infarction

We identified two studies of post-myocardial infarction programs containing economic information.[71, 72] Both programs assessed home-based rehabilitation as an alternative to traditional rehabilitation programs.

The study of DeBusk[71] compared the medically directed at-home rehabilitation training with a group rehabilitation and two no-training intervention arms (one with exercise testing but not subsequent exercise training, and one with neither testing nor training). Their targeted population was male patients aged 70 or younger with a clinically uncomplicated acute myocardial infarction (AMI). Compared to group rehabilitation, patients assigned to the medically directed at-home rehabilitation had about equally high adherence to individually prescribed exercise, increase in functional capacity, and equally low nonfatal reinfarction and dropout rates. Compared to the no-training groups, the patients randomized to the two training groups achieved significantly greater increases in functional capacity, but there was no difference in cardiac events. The cost for the three months of at-home rehabilitation in this study was estimated to be approximately $328 per patient (1983 dollars, about $885 in 2002 dollars). In contrast, the group rehabilitation program was approximately $720 ($1,945 in 2002 dollars). Thus the authors claimed that, compared to group rehabilitation, medically directed at-home rehabilitation has the potential to increase the availability and to decrease the cost of rehabilitating low-risk survivors of AMI.

The study by Lewin[72] examined whether a comprehensive home-based program reduced psychological distress and use of health services. Subjects randomized into the self-help rehabilitation program were given a heart manual that included education, a home-based exercise program, and a tape-based relaxation and stress management program. Also included were specific self-help treatments for commonly experienced psychological problems among post –MI patients. Spouses were given materials to support and encourage compliance by patients. A treatment facilitator provided follow-up and feedback to potentiate self-help treatments. In the control group, subjects received standard care plus a placebo package of information and

informal counseling. Besides finding better psychological adjustment in the rehabilitation group than the control, the authors reported significant differences in the use of health services. The rehabilitation group made significantly less GP consultations in the one-year follow-up (a mean of 1.8 less visits than did the control group in the first 6 months, and a mean of 0.9 less visits in the subsequent 6 months). In addition, significantly more control patients than rehabilitation group patients were admitted to the hospital in the first 6 months (18 vs. 6) but not significant at the second 6 months (18 vs. 9).

Costs of the intervention were not assessed rigorously, but the authors estimated it to be £30 - £50 (roughly $100 to $165 in 2002 dollars). The authors claimed that the modest costs of the self-help program might well be balanced by the reduction in GP consultations and hospital admissions. The caveat of this result is that the use of health services was based on patients' general practitioners self-report, so the reliability and validity is uncertain. In addition, as an alternative to hospital-based program, the cost-effectiveness of the home-based program should be compared with that of a hospital-based program.

Non-disease-specific Programs

Three RCTs provided self-management programs to general chronically ill patients were identified to include economic evaluation.[73-75] One intervention setting was within healthcare organization,[74] another was community-based,[75] and the other was collaboration between primary care providers and community center.[73] The latter two showed significant reductions in hospital use (including number of hospitalized patients, number of hospitalizations, and inpatient hospital days). From a societal perspective, such reduced hospital use may result in the two CDSM programs being cost-saving interventions (i.e., the savings in hospital utilization offsets

the cost to provide interventions). Nevertheless, rigorous cost-benefit or cost-effectiveness analyses were not done.

The primary care-based intervention, called "Chronic Care Clinics" for frail older adults, did not find significant differences in healthcare costs or utilization between intervention and control groups.[74] Besides methodological reasons to explain these findings, the authors attributed these results to a hindrance in implementation of this intervention due to major changes in the delivery system under study. These changes resulted in a lack of continuity and support of clinical and administrative staff and thus undoubtedly influenced the ability of the study to demonstrate more positive effects on patient outcomes and utilizations.

A geriatric nurse-led "care manager" model that involved collaboration between primary care providers and a community center reported beneficial reductions in hospital use, and should be further examined.[73] The utilization differences were of borderline statistical significance (see Appendix evidence table). The study did not report beneficial findings on two outcome measures – physical performance and overall health profile (as measured by SF-36). Additional studies seeking to replicate or explain these findings are warranted.

The other program, the community-based Chronic Disease Self-Management Program (CDSMP), was an extensive educational course with skills training, feedback, and group support. It was designed for people who had lung disease, heart disease, stroke, arthritis, or diabetes. The program approach did not differ by disease type. This program reported decreases in healthcare utilization in the randomized clinical trial,[75] and in two additional observational studies. One study used a before-after cohort design,[76] and the other study was a longitudinal design intended to follow-up patients enrolled in the randomized trial.[77] According to the authors, all three studies were likely to be cost-saving from a societal perspective. However, this conclusion is

tempered as none of the studies performed a rigorous cost-benefit analysis. In addition, the studies differed in what aspect of utilization was reduced. The randomized clinical trial[75] significantly decreased the number of hospitalizations and length of hospital stays. The before-after cohort study found the study participants had fewer visits to the emergency department.[76] The longitudinal study reported a reduction in combined ER/outpatient visits.[77] Compared to the other two RCTs,[73, 74] the CDSMP was provided to younger populations. The mean age of the study participants was about 65 years old, while the mean age was about 77 years old in the other two RCTs.

Critiques and Conclusions

These reviewed interventions from clinical trials represent only a subset of possible strategies for CDSM. This economic review has limited generalizability beyond the studied interventions. Critiques about the economic aspect of CDSM literature include:

1. Costs of the intervention are rarely reported and, when reported, was sometimes not rigorously performed (e.g., by author's best approximation; perspective of costing was inconsistent; time costs to patients and providers were not fully accounted);
2. Health care costs as an outcome of the intervention were rarely studied;
3. Changes in health care utilization were seldom studied, and in many cases only studied on a limited scale (not including all types of services);
4. The follow-up period is short, while many outcomes will not be evident for many years (e.g., rigid metabolic control may result in a delay or prevention of diabetic complications, but only after several years).

Among the four diseases reviewed, the programs to promote self-management with osteoarthritis patients have the best economic information and are most consistently reporting reductions in health care utilization and costs, even to the point of cost-savings. Such findings are compatible with observational studies.[14-16] Programs for diabetic patients have mixed results, and overall are weaker in the economic information they report. There is only one hypertension program identified that include any economic information, and the information provided does not allow us to adequately judge cost-effectiveness of the program. The two reviewed MI studies both lacked a rigorous collection of economic data, but the limited evidence presented suggests that home-based rehabilitation programs could potentially be a cost-effective alternative to group rehabilitation or standard care. As for the three general, non-disease-specific programs, two RCTs and two observational studies reported that low-cost, community-based CDSM programs may potentially be cost-saving.

Question 14. Delivery mechanism: What do we know about whom (which provider type? trained lay person?) should deliver this service? Do we know which care settings have proven effective (e.g., physician's office, senior center, other community or clinical settings)?

Successful CDSM programs have been delivered by both medically-trained providers and by training lay people, and have been performed in (list the settings that have positive studies). However, we were unable to find evidence to support generalizing the finding of these individual studies to policy.

LIMITATIONS

Despite finding evidence that CDSM programs have a clinically and statistically significant beneficial effect on some outcomes, we were unable to discern which elements of CDSM programs are most associated with success. This may have been because we did not test the right hypotheses regarding CDSM elements, or because key variables describing these components were either not recorded adequately or not recorded at all in the published articles, or that the individual components themselves each have relatively weak effects. We considered contacting original authors for additional information regarding their interventions, but rejected this due to time and resource constraints. Furthermore, our experience has been that any study published more than a few years ago has a much lower likelihood for getting a favorable response to such a request, and 524 of our studies were published more than 10 years ago. In addition, we may have lacked the statistical power, due to the small number of studies available, to discern the reasons for the relatively small amount of heterogeneity in the study results. We note that the preceding challenges are common to all studies of complex, multicomponent interventions, and these challenges did not prevent us from detecting important differences in the effectiveness of interventions for prevention of falls[17] or increasing the use of cancer screening and immunizations.[18]

An additional primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in self-management (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and their relationship to bias, we did not attempt to use other criteria.

As previously discussed, we did find evidence of publication bias in hemoglobin A1c, mortality, and systolic and diastolic blood pressure outcomes in diabetes, post-myocardial infarction care, and hypertension, respectively. Therefore, the beneficial results that we report in our pooled analysis need to be considered in light of the possible existence of unpublished studies reporting no benefit.

CONCLUSIONS

1. Chronic disease self-management programs probably have a beneficial effect on some, but not all, physiologic outcomes. In particular, we found evidence of a statistically significant and clinically important benefit on measures of blood glucose control and blood pressure reduction for chronic disease self management programs for patients with diabetes and hypertension, respectively. Our conclusions are tempered by our finding of possible publication bias, favoring beneficial studies, in these two clinical areas. There was no evidence of a beneficial effect on other physiologic outcomes such as pain, function, weight loss, and return to work.

2. There is not enough evidence to support any of the proposed elements as being essential to the efficacy of chronic disease self-management programs. More research is needed to try and establish the optimum design of a chronic disease self-management program, and whether or not this differs substantially depending on the particular chronic disease or characteristics of the patient. Of note is that all of the studies we reviewed assessed chronic disease self-management delivered as part of an organized program. In other words, we did not identify an assessment of a chronic disease self-management program designed to be delivered in a single physician's office or small group practice.

3. While no randomized studies of chronic disease self-management programs for older adults assessed the use of email or the Internet, one recently reported randomized study of email use in the self-management of middle aged adults with back pain was sufficiently promising to warrant testing such interventions for chronic disease self-management in the Medicare population.

4. There is no evidence to conclusively support or refute the role of physician providers in chronic disease self-management programs for older adults.
5. The evidence is inconclusive but suggests that chronic disease self-management programs may reduce health care use.

RECOMMENDATIONS

1. There is sufficient evidence to support a pilot program promoting chronic disease self-management programs for older adults.

2. However, before implementing such a pilot program, additional work is needed to optimally define the essential elements of such programs, and whether they vary by condition or patient characteristic. It is more than likely that any successful chronic disease self-management program will need to be delivered in the context of an organized system of care, or else external to the traditional solo or small group practice physician.

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APPENDIX A. EXPERT PANELIST

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APPENDIX B. ACCEPTED ARTICLES

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APPENDIX C. REJECTED ARTICLES

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EVIDENCE TABLES