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Functional Status in Older Adults: Intervention Strategies for Impacting Patient Outcomes

Technical Report

Literature Review Supplement for MAO Guide on Opportunities for Improving Medicare HOS Results through Practices in Quality Preventive Health Care for the Elderly

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I. Overview of Literature Review

This literature review is a synthesis of selected articles of functional status outcomes in older adults and designed to supplement the guide developed by the National Committee for Quality Assurance for Medicare Advantage Organizations entitled, "Opportunities for Improving Medicare HOS Results through Practices in Quality Preventive Health Care for the Elderly." The included outcomes target short form assessments of health that span the physical to psychological from well established questionnaires such as the SF-36 and SF-12. In addition, outcome measures that capture functional limitations in Medicare Advantage recipients include activities of daily living. The articles were selected from the vantage point of interventions that could impact on the functional status outcomes in elderly populations. The Medicare Health Outcomes Survey (HOS) includes the Veterans Rand 12 Item Health Survey (VR-12) as the core measure and includes HEDIS® Effectiveness of Care Measures for Management of Urinary Incontinence in Older Adults, Physical Activity in Older Adults, Fall Risk Management and Osteoporosis Testing in Older Women. These measures were selected because they address clinical issues that are highly prevalent in older adults and that effective management of has the potential to either slow or reverse the functional decline in these patients. We have included in this review interventions that are focused on patients diagnosed with specific medical or mental morbidities, as well as those that are more broadly based, addressing those with a range of sociodemographics and accompanying conditions. For interventions reported as having positive impacts on functional status, we give the relative clinical importance of the intervention when data are present; effects are described in the small, moderate and large ranges. Small effects are about 2 points, moderate effects are about 5 points and large effects are defined as 8 points or greater on the physical (PCS) and mental (MCS) summary scores captured by the VR-12 and equivalent to the summary scores using the SF-36 and SF-12.

There were two major goals to this review. The first was to present intervention studies that demonstrate an impact on the physical or mental health of geriatric populations that either slow or reverse the progression of decline in these patients and are fairly comparable to the profile of enrollees in Medicare Advantage (MA) Organizations. The second goal is to provide some integration of the overall findings so that recommendations regarding intervention impacts can be made for use by quality improvement managers, administrators, and clinicians of plans.

Sections II thru V of this report are composed of a description of interventions based upon selected medical and mental health related studies that warrant a description (given the rigor of the study) of the interventions and outcomes using HRQoL assessments with some emphasis on short form metrics (SF-36®, SF-12®, VR-36 and VR-12). We have also included a description of studies with emphasis on selected HEDIS measures that are included in the HOS.

The next part of this report reflects a comprehensive literature review spanning studies over the past decade using a systematic review approach. This review is to supplement the first part of the report. We chose not to conduct a formal meta-analysis given the limitations of the articles. We

have attempted to provide a comprehensive search and reporting of a few hundred articles giving the key elements of the design, the nature of the intervention and findings. On the basis of this review we have highlighted articles that provide good examples of small, moderate or large effects on the short form metrics. This encyclopedia of many articles is categorized by specific clinical/diagnostic areas for use by health care providers and administrators of plans as they go forward in planning strategies to impact the health outcomes of their enrollees in the Medicare Advantage program.

II. Older Adults: Demographic Profile and Accompanying Health Conditions in Medicare Advantage Organizations

CDC has previously reported that at least 95 million Americans have a chronic disease diagnosis and that chronic conditions account for about 65% of all deaths in the U.S. (Centers for Disease Control and Prevention 2010).

Enrollees in the Medicare Advantage program, as reflected by three HOS cohorts (cohort 2 1999-2001, cohort 3 2000-20002, cohort 4 2001-2003) are on average 74 (+/- 6) years of age, 89% are white, 6.4% African Americans and 1.8% Hispanics. 77.4 % are married and 30.7% are with less than a high school education. 41.9% have less than an annual household income of $20,000 (Selim et al., 2010). Comorbidity profiles for the more prevalent conditions occurring in this elderly population (an indication of functional limitations and needs of the MA enrollees) ranged from 0 to 8 co-morbidities (9.5% with 4 or more, 11.2% with 3, 21.2% with 2, and 32.4% with one). The most prevalent reported condition included hypertension (52.2%) followed in descending order by angina (20.7%), diabetes (19.8%), coronary artery disease/myocardial infarction (15.7%), cancer (15.1%), chronic obstructive pulmonary disease/asthma (13.5%), stroke (9.3%), and chronic heart failure (8.7%). These results reflect an aging geriatric population with concomitant conditions that are quite prevalent and require ongoing medical treatment with important consequences for health outcomes.

III. Interventions Targeting Functional Status in Elderly Populations Based upon Short Form Assessments

A framework for impacting the functional status in elderly populations based upon short form assessments, such as the VR-12 physical and mental health summaries (PCS and MCS), include the following: (1) identifying prevalent conditions with high impact on the health of the elderly, (2) implementing approaches for screening for identified medical or mental health priorities, and; (3) following-up with intervention strategies designed to target such populations. The resulting targeted interventions provide opportunities for impacting changes in PCS and MCS scores so that previous decline is slowed or stabilized or in the best of circumstances reversed. There are many studies that have been performed over the past 2 decades from which we have selected a small number to illustrate the impacts of certain interventions. Articles were selected with an eye towards identifying similar populations as in the Medicare Advantage program. We included more rigorous studies that include randomized trials and quasi-experimental observational studies with comparison groups and appropriate adjustments to rule out confounding. Medical and mental health interventions ranged from those that are more specific and target discrete

diagnosed populations to those interventions that are more behavioral based and span a range of conditions and socio-demographics.

A. Variables Associated with Health Status Changes in Older Populations

Studies examining the relationship between patient demographic and clinical characteristics with physical and mental health in older patients are for the most part cross-sectional. There are a few that are longitudinal cohort studies. Using the Medicare Health Outcomes Survey, Cooper et al. (2001) reported that heart and lung disease, as well as back pain are the most important determinants affecting PCS and MCS scores. The addition of a number of conditions and symptoms explained as much as 58% of the variability. Interestingly, sex, marital status and race/ethnicity explained much less in terms of independent explanatory effects (8%). The variable 'shortness of breath climbing one flight of stairs' explained the largest variation in PCS scores in multivariate models (31.2%). The second most important factor was back pain associated with PCS scores (11.9%). Results suggested that managers and clinicians should focus on interventions designed to impact disease processes, such as symptoms related to diagnoses most likely to impact the functional status of the elderly. Demographic characteristics appear to contribute in a much smaller way to the level of functional status. In other earlier studies by Kazis et al. (1998, 2006), results of cross-sectional analysis predicting physical function using the SF-36 in veterans who used the Veterans Health Administration showed that demographic characteristics were much smaller in their association with levels of health than symptoms and self reported diagnoses.

In a previous review by Stuck et al. (1999), the top three risks identified related to functional decline were cognitive impairment, diagnosed depression and the disease burden defined as co-occurring illnesses.

In a separate HOS study with MA enrollees, Ellis et al. (2004) researched the predictors of changes in PCS and MCS over two years of follow-up using change scores.
The largest declines in PCS functioning were attributed to arthritis of the hip/knee, sciatica and emphysema/asthma/chronic lung disease (COPD). Incident cases defined as newly diagnosed chronic conditions between baseline and follow-up were associated with declines in PCS and MCS. Further, the baseline PCS and MCS scores, as an indicator of disease burden and case mix complexity, explained much of the variability in the change score. The multivariate models explained a small amount of the variability in the functional status changes. Of note was that enrollees with several medical chronic conditions accompanying risk for depression demonstrated the greatest decline in mental functioning. Mortality also needs to be considered in measures of functional status, where measures of mortality explain differences in PCS and MCS by as much as 11 points lower for PCS and 5 points for MCS, about one standard deviation (SD) and ½ of a SD, respectively. Sicker patients are at greater risk of mortality and have lower levels of PCS and MCS at baseline. Those particularly at higher risk of mortality are at risk for a steeper decline in functional status outcomes.

To summarize, chronic conditions and symptoms are most likely to impact PCS and MCS functional status decline. Those administering MA programs might focus on those enrollees with

chronic conditions/symptoms described and consider intervention strategies targeting these groups to mitigate the course of PCS and MCS decline.

Ellis et al. (2004) concludes by saying that the use of a Chronic Care Model (Wagner et al., 2001) gives a framework for targeting interventions designed to impact on the trajectory of functional status with implications for populations not unlike those found among Medicare enrollees. Some of the key components of this model include improving patient level care through clinical practice and focus on the organization and practice of care. The interventions presented in this review were selected in part on the basis of this framework.

B. Medical Interventions in General Geriatric Populations

Medical interventions are wide ranging and with mixed results as to their impacts on the functional status of elderly populations. The SF-36®, SF-12®, VR-36 and VR-12 can be used as assessment tools to measure health related quality of life in many interventions, especially those in which evaluation and management of clinical practices are the focus. In providing measures of functional status in patients, short assessment tools can help practitioners improve medical treatments and procedures to have a positive effect on health status and health related quality of life in general elderly populations. Results in these populations are not conclusive but do suggest that functional decline can be reduced through inpatient and outpatient geriatric evaluation and management and integrated/ home based geriatric care management.

A one year controlled trial (Cohen et al., 2002) studying the differences between inpatient and outpatient geriatric care used the SF-36 to determine that care provided in either clinic setting had no effect on survival in older patients, though inpatient care significantly reduced functional decline. The SF-36 was used to measure survival and health-related quality of life in frail veterans over 65 years of age who were randomized and assigned to receive usual care or care in an inpatient geriatric unit. There were no synergistic effects between any of the 1388 patients in the two interventions, though at the end of the one year trial patients in the intervention group had higher scores in four SF-36 scales. In a separate study the SF-36 was used to show that more favorable self-reported satisfaction outcomes occur in Medicare patients exposed to population-based disease and case management programs over a one year period (Martin et al., 2004). In evaluating the effect of population-wide disease and case management on resource use, health status, and member satisfaction in a Medicare Advantage plan, the SF-36 was used in a randomized control trial in participants 65 years and older. Eight thousand five hundred four (8504) Medicare beneficiaries, who were enrolled in a HMO plan for over 12 months, were enrolled in the open trial for 18 months to determine self-reported health status. The results showed that the intervention group was more satisfied with the health plan ($p < .01$) and social function ($P = .04$). The study found that "population-based disease management and case management led to improved self-reported satisfaction and social function but not to a global net decrease in resource use or improved member retention." (Martin DC, et al., 2004). In yet another study (Counsell SR, et al., 2007), the SF-36 was used in a randomized clinical trial to evaluate a geriatric care management model's effect on quality of life for low-income seniors and concluded that quality of care was improved while acute care utilization decreased in the intervention group. SF-36 measures revealed significant improvement in SF-36 scales of the intervention group in four of the eight scales when compared with the usual care group: general

health, vitality, social functioning and mental health (all 4 scales, $p < 0.001$). Positive differences were small effects.

B.1 Selected Interventions Related to Pulmonary Rehabilitation

In measuring the effects of pulmonary rehabilitation on functional status results indicated that measures of functional outcomes were impacted positively, with moderate to large impacts on clinical measures and functional status.

In a study of pulmonary rehabilitation in patients with chronic obstructive pulmonary disease (COPD), use of the SF-36 questionnaire determined that a 3-week comprehensive pulmonary rehabilitation program resulted in improved quality of life in program patients (Boueri et al., 2001). The program incorporated twelve exercise sessions, education, and psychosocial counseling, and results showed an improvement in the majority of SF-36 subscales following pulmonary rehabilitation. In another community based pulmonary rehabilitation study, a randomized trial studied the effect of pulmonary rehabilitation after hospitalization for COPD patients and used the SF-36 to show that early pulmonary rehabilitation after hospital admission lead to significant improvements in health status.

Early rehabilitation led to improvements in the mental component score of the SF-36 when compared with patients receiving usual care ($p=0.02$) at 3 months, the differences between groups were large and clinically meaningful (Man et al., 2004).

B.2 Selected Interventions Related to Cardiac Rehabilitation

In some studies, measuring physical and mental health improvements after a cardiac rehabilitation intervention, selected studies have reported positive impacts on functional status using the SF-36 in both the small and moderate range of effects.

An 8-week cardiac rehabilitation program for patients with acute myocardial infarction using the SF-36 questionnaire showed marked improvements in functional status and patient's well-being. In the same cardiac rehabilitation program in patients with a previous acute myocardial infarction (AMI), subjects had aerobic exercise and moderate resistance training from 1 to 3 months following their AMI. Significant improvements were seen in four of the eight SF-36 subscales in the intervention group (physical functioning, general health perceptions, role-physical and vitality). Impacts were all positive and significant with effects in the small to moderate range (Izawa, 2004).

In a separate randomized controlled trial, elderly patients with coronary artery disease (CAD), were given a phase III cardiac rehabilitation intervention (CR). The SF-36 measured significant improvements in bodily pain, general health, vitality, and mental health ($p<0.05$) in those given the intervention group compared to the control group. Positive changes were in the moderate range (Seki, 2003).

B.3 Selected Interventions Related to Populations with Arthritis

Arthritis is a prevalent condition in elderly populations often diagnosed as rheumatoid or osteoarthritis with musculoskeletal complications frequently described as a downward trajectory of functional status with accompanying symptoms such as pain and fatigue. A mix of interventions such as physical exercise in the context of aerobics, aquatics and even acupuncture have demonstrated small and moderate positive effects.

In a randomized controlled trial using a home-based exercise program for patients with osteoarthritis and knee pain, the conclusion was that such an interventional program can significantly reduce pain and improve quality of life. Subjects were randomized to four groups, receiving physical therapy, a monthly telephone interview, therapy plus a phone call, or no intervention. Results reported SF-36 physical function significantly improved while pain related symptoms were reduced in the exercise group when compared with the non-exercise groups, differences were in the small to moderate range (Thomas et al., 2002).

In another study, patients diagnosed with rheumatoid arthritis who exercised in a temperate pool for twelve weeks showed marked improvement in vitality ($p<0.05$) when compared to patients who continued previous care activities. Patients were randomized to receive either exercise treatment or no treatment for twelve weeks and measured for aerobic and muscle strength. Significant improvements in the SF-36 vitality domain of the treatment group were seen when compared with the control group. Investigators concluded that aquatic exercise therapy "significantly improved muscle endurance" in RA patients (Bilberg et al., 2005).

In a novel randomized controlled trial using acupuncture, patients diagnosed with osteoarthritis of the knee or hip benefited from a three-month trial that added acupuncture to routine care. Patients were randomized to undergo as many as 15 sessions of acupuncture (combined with routine care) or routine care alone. The SF-36 physical component summary assessed at baseline and 3 months, improved significantly more in the acupuncture group when compared to the control group ($p < 0.001$), in the moderate range. The mental summary score was significantly better for the acupuncture group for all subjects generally and more specifically for those with arthritis of the knee ($p< 0.05$), in the small range. However, results were not significant at 6 months (Witt et al., 2006).

B.4 Selected Interventions Related to Populations with Mental Health Problems

Single prong interventions such as patient screening, provider education, talk therapy, exercise feedback and alternative treatments have been shown to have small impacts on behavioral health. Recommendations are for bundled interventions that include several therapies administered concurrently to demonstrate larger clinical impacts using functional status as the outcomes. Two studies building on the chronic care model for patients with depression and Alzheimer's disease are selected and shown to have positive impacts on functional status (APA Guidelines for depression and Alzheimer's disease, 2010).

B.4.1 Depression

In an important 9 month randomized trial of 'collaborative care' for treatment of depression, a mental health team created a treatment plan with a primary care provider, and enfranchised the patients in this process with suggestions for adherence, gathering results, and suggesting plan modifications back to the provider. Results showed that the "collaborative care group" demonstrated statistically significant improvements on the SF-36 mental summary score compared with usual care (consultant – liaison care) at nine months ($p<0.05$). Differences were reported as moderate effects and deemed clinically important. In addition, those in the collaborative care group demonstrated an increased proportion of patients receiving prescriptions and cognitive behavioral therapy. (Hedrick et al., 2003).

B.4.2 Alzheimer's Disease

In a five year randomized trial, of community dwelling elderly, 153 patient-caregiver teams were randomized to routine medical care or a combined exercise and a caregiver training program for three months. At the end of the study, patients in the intervention group exercised more (OR: 2.82; 95% CI, 1.25-6.39; $p=0.01$) and had fewer days of restricted activity (OR: 3.10, 95% CI, 1.08-8.95; $p<0.001$) than those in the control group of usual care. Importantly patients in the intervention group had improved SF-36 physical role functioning scores compared to the control group (mean difference, 19.29; 95% CI, 8.75-29.83; $P<0.001$) in the first 3 months and importantly at 24 months of follow-up differences persisted in the favorable direction, (mean difference, 10.89; 95% CI, 3.62-18.16, $p=0.003$). The investigators concluded that the intervention of exercise training combined with behavioral management "improved physical health and depression in patients with Alzheimer disease." Effects were as large as 50% of a standard deviation difference for selected domains of health, reflecting a moderate clinically important improvement (Teri et al., 2003).

B.5 Other Selected Novel Interventions

The following selected interventions include behavioral therapy and exercise training, and the use of yoga in healthy seniors. The impact on functional status with multi-intervention approaches is in the moderate to large range for clinically and socially relevant effects.

B.5.1 Behavioral Therapy and Exercise Training

In a randomized 24 month trial of combined behavioral therapy and exercise training versus control groups, obese older adults were given either weekly behavioral therapy and tri-weekly exercise therapy or no intervention. The combined therapy resulted in improvements in the physical and mental summaries of the SF-36 post-intervention at 6 months. However, at later follow-up at one and two years, the physical composite scale regressed to baseline levels. Importantly, the mental summary scale was sustained at levels significantly higher than baseline ($p<0.05$, with Bonferroni corrections). Results reported for mental health changes were in the moderate range of positive effects (Villareal et al., 2006).

In another related study, a 2-year randomized controlled trial with a "behavior change-focused weight management program" measured the effect of weight loss and exercise in frail obese older adults. All participants in the trial received six months of participation in a clinical weight loss program that was a bundled set of clinical interventions and were then randomized into two 6-month care groups to receive more of the intervention or none. Results showed positive significant impacts in the intervention group as contrasted with the control for SF-36 physical function, role limitations due to physical problems, bodily pain and vitality ($p<0.05$). Effects were in the moderate range of clinical effects (Blissmer et al., 2006)

B.5.2 Yoga Exercise

In a randomized controlled six month trial of yoga in healthy seniors, subjects were randomized to Hatha yoga class, a walking exercise class, or a wait-list control group. While there were no significant impacts demonstrated for the most part for the cognitive measures (including alertness and attention), "the SF-36 quality-of-life measure demonstrated a significant yoga assignment group effect on vitality/energy and fatigue
($p =0.006$), role-physical ($p = 0.001$), bodily pain ($p = 0.006$), social functioning ($p= .0015$), vitality ($p=0.006$) and the physical summary scale ($p=0.005$)." The effects demonstrated were in the small range (Oken et al., 2006).

IV. Interventions that Impact Activities of Daily Living (ADL) in Disabled, Older Populations

Activities of daily living are metrics administered to populations with more disabling conditions. There is a long history of their use and in this section of the review we have selected interventions targeting older frail populations. In elderly populations, ADLs help determine what type of long-term care and coverage a patient might need. It is important to measure basic ADL scores in elderly populations at increased risk for morbidity or mortality. There are six ADL items in the HOS and the briefer HOS-Modified (HOS-M) surveys, including difficulties with bathing, dressing, eating, getting in or out of chairs, walking and toileting. These ADL items expand on the items used in the VR-12. They are used by the HOS for purposes of defining enrollee populations with greater needs. The HOS focuses on a broad sampling of MA enrollees, while the HOS-M focuses on frail and elderly beneficiaries in the Program of All-inclusive Care for the Elderly (PACE) program. The ADL measures are used by CMS to provide case mix adjustments for purposes of payment using a frailty adjustment factor. We have restricted this review to interventions designed to impact on the disabled frail elderly populations that may require greater resources. Interventions designed to impact on this targeted population are important in their own right for impacting functional status measures.

A. Interventions in General Populations of Elderly

As the number of individuals over the age of sixty-five continues to increase in the United States, it is important that health interventions and prevention programs address the vital health care needs of the elderly, especially those with disabling conditions. The increasing amount of health care services required to maintain optimal health and decrease the impact of morbidities is a

problem that is best addressed by health assessments or screenings and interventions designed to reduce the risks of morbidity and mortality.

In an early randomized control trial, Stuck et al. (1995) assessed the effect of in-home geriatric assessments on prevention of disability in individuals over 75 years living in California. The three year trial included 215 elders living in the community who were randomized to be seen at home by gerontologist nurses (working in collaboration with geriatricians), who evaluated risk and disability and gave recommendations. In measuring disability prevention, defined in the study as "the need for assistance in performing the basic activities of daily living," the trial found that in-home geriatric assessments have the ability to delay disability and reduce the need for permanent nursing home stays in elderly community dwellers (adjusted OR, 0.4; 95% CI; 0.2 to 0.8; p=0.02).

In a later landmark study of a randomized trial of in-home visits for disability prevention in community dwelling elderly at risk for nursing home admission, Stuck et al. (2000), showed that in-home visits by nurses (in collaboration with geriatricians) has the potential to reduce disability in the elderly at risk for functional impairment and the need for nursing home admission. The randomized trial examined participants who were community-dwellers over the age of 75 at both low and high risk for full-time care, and risk status was determined by baseline characteristics of functional deterioration. Each participant was seen quarterly by a nurse, who, "gave recommendations, facilitated adherence with recommendations, and provided health education." After a 3 year study, the results of this evaluation suggest that the intervention can reduce disabilities in people at low risk (OR 0.6; 95% CI, 0.3-1.0; P=.04), but does not affect those at high risk for impairment. For those at low risk, impacts of the intervention were in the low to moderate range.

In yet another important article by Stuck et al. (2002), a meta-analysis was conducted to evaluate the effects of home visitation programs on functional status, nursing home admission, and mortality in elderly adults. The analysis examined 1349 abstracts in five languages that reported randomized trials on the effects of preventive in-home treatments in older community-dwelling populations. After exclusions were made, two reviewers independently screened the remaining 17 articles for information on functional status, nursing home admission, and mortality among study populations. The combination of trials using multi-dimensional ADL assessments and follow-up gave a 24% reduction in the risk of functional decline. (RR, 0.78; 95% CI, 0.64-0.94). The group concluded that such home visitation programs "appear to be effective, provided the interventions are based on multidimensional geriatric assessment and include multiple follow-up home visits and target persons at lower risk for death." The chronic care model in this study provides an important rubric for multi-dimensional geriatric assessment that were the most important factors that retarded the progression of functional decline.

In another milestone article in the ADL literature, Tinetti et al. (1994) conducted a study to assess the use of a multi-factorial intervention in the reduction of fall risk among elderly adults living in the community. Three hundred one (301) adults over the age of 70 who had one or more risk factors for falling were given either usual health care or a combination of medication adjustment, behavioral instruction, and exercise programs. During one year of follow-up, the incidence rate for falling in the intervention group was 0.69 as compared to the control group

(95% CI, 0.52-0.90). The multiple-risk-factor intervention study yielded a significant reduction in the risk of falls among older people in the community, and the proportion of people with targeted risk factors for falls was reduced in the intervention group. This important study set the stage for the use of the chronic care model and is applied to evaluate elderly patient's health using multi-factors for the intervention combining behavioral instruction, exercise and medication adjustments. This approach was novel and incorporated nurse practitioners, physical therapists and the physician with health care in the home.

B. Stroke

Strokes can have major life changing impacts on individuals' activities of daily living. Interventions aimed at reducing disability time and morbidity after strokes are well documented in the literature. We have selected several meta-analyses conducted that focus on occupational therapy, therapeutic exercise for subacute stroke survivors and the impact of intensity of augmented exercise therapy time on ADLs. In studying the effects of these trials plan managers can consider interventions that have impacted functional decline in the elderly with strokes.

Walker et al. (2004) conducted a pooled meta-analysis on the basis of 8 single-blind randomized controlled trials that included 1143 patients, to determine the effectiveness of occupational therapy in stroke survivors on ADLs. The trials used the Nottingham Extended Activities of Daily Living (NEADL) as a well established ADL metric. The analysis found that occupational therapy yielded higher NEADLs at the end of the intervention (Weighted Mean Difference (WMD) 1.30 points, 95% CI; 0.47-2.13) and higher leisure scores (WMD 1.51 points, 95% CI; 0.24-2.79). In addition, where ADL activities were emphasized as part of the intervention, results were higher indicating improved NEADL scores (WMD 1.61 points, 95% CI; 0.72-2.49). Occupational therapy improves personal activities of daily living for stroke sufferers, and more significant outcomes were found in more targeted interventions. Stroke patients performed at higher levels of ADL with the use of occupational therapists. The results were clinically important since the impact of 1.3 points indicates the ability to perform an activity independently such as household chores or walking outdoors. In this instance the authors deemed 1 point to be clinically important.

In another meta-analysis, Kwakkel et al. (2004) conducted a systematic review and identified 20 studies that included 2686 stroke patients. The focus was on augmented effects of the intensity of exercise therapy on ADL, gait and dexterity. The results showed small but significant positive effects restricted to therapies targeting lower limbs and ADL in general at 6 months after stroke. When an additional 16 hours of exercise therapy time is provided, a small effect of 4-5% is reported in ADL.

In a randomized control trial of stroke survivors, Studenski et al. (2005) reported that the effect of therapeutic exercise on quality of life over a twelve week program post stroke led to more rapid improvement in function and quality of life. In this rigorous study, the Barthel index, Functional Independence Measure, Instrumental Activities of Daily Living and the SF-36 were employed as outcomes measures in a secondary analysis of a randomized control trial of exercise in subacute stroke patients. The twelve-week study randomized 100 subjects into a home based exercise program with the support of occupational or physical therapist against a program of

usual care. The therapists focused on strength, balance and endurance with emphasis on use of the affected upper extremity if impacted. Effects were in the small to moderate ranges, with physical functioning as much as 61% of a standard deviation improvement. The effects diminished 6 months after the intervention stopped. The rehabilitation exercise program resulted in improvement in aspects of functional status and in particular physical functioning than usual care in subjects with subacute stroke. Results suggested that a sustained program can have important positive physical functioning effects in improvement in those with stroke.

A meta-analysis by French et al. (2010) involving fourteen clinical trials was conducted to determine if the use of repetitive task training (compared to usual care) improves functional activity in stroke patients. Each randomized trial included the use of an active motor sequence aimed at improving functional activity after stroke for a single training session. Citing the difficulty of classifying "interventions involving elements of repetition and task training," results of the analysis indicated that repetitive task training gave only modest improvement in functional activity across a range of lower limb outcome measures, but not in upper limb outcome measures. Improvements are reported for walking distance, walking speed, sit-to stand, and activities of daily living. Differences were modest however judged to be clinically important.

Results of these studies that include randomized clinical studies, systematic reviews, and pooling studies strongly suggest that a combination of interventions in the clinic and home that are multi-component and utilize multi-disciplinary staff (e.g. physicians nursing staff, occupational and physical therapists) often result in effects that are moderate and clinically important with positive impacts on functional status in the more disabled frail elderly.

V. HEDIS Effectiveness of Care Measures in the HOS

This section of the review focuses on the content of four HEDIS measures included in the HOS. These include urinary incontinence, exercise or physical activity, falls, and osteoporosis. Selected studies include positive impacts of tailored interventions for each of these areas on PCS and MCS.

A. Urinary Incontinence (UI)

The specific HEDIS items for urinary incontinence (UI) in the HOS include presence of a urinary leakage problem, how big a problem this is, whether the subject has spoken to their doctor or health provider about this, and finally whether this problem has been treated. The selected literature focuses on the impact of interventions on UI and its impact on PCS and MCS as the outcomes.

Estimates of the prevalence of UI in the community range from 21% to 39% among women and 5% to 32% among men varying by clinical definition, populations studied, methods for assessment, response rate and age range (NIH State-of-the Science Conference Statement, 2007.). A comprehensive evidence report on the Prevention of Fecal and Urinary Incontinence by the Minnesota Evidence-based Practice Center (2007) reports an age related prevalence with the highest being 32% in males 65 years and over, while for women 65 and over the prevalence is up to 39%. The National Health and Nutrition Examination Survey (NHANES) report that

about 30% of women above age 65 years have bladder control problems and 15% of the men also 65 and over reported this problem. Treatments or interventions for UI include medication therapies, behavioral, electrical stimulation, surgical, and palliative/supportive treatments. Studies also indicate an association between incontinence and impaired cognitive or physical functioning (Fultz et al., 2001).

Intervention studies reflect for the most part small effects on functional status. The alleviation of symptoms such as urgency, nocturia, urge incontinence, stress incontinence, difficulty passing urine, bladder pain and intercourse incontinence are conceptually related to functional status and wellbeing. Mardon et al. (2004) reported results in the Medicare Advantage HOS survey that PCS and MCS scores using the SF-36 were significantly lower for those reporting problems from UI and ranged from small to large effects, cross-sectionally. Small problems were associated with unadjusted PCS differences of -4.5 points and -10.5 points for large problems. For MCS, differences were -3.3 points and -8.4 points for small and large problems, respectively. Adjusted analysis examining big problems was -5.1 points suggesting a mean reduction of about 51% of a standard deviation on the PCS scores for subjects with a large UI problem after controlling for age, sex and race. For MCS scores adjusted differences were -5.0 points for large problems. These differences were considered clinically relevant cross-sectionally in the moderate and large range. The SF-36 subscales giving the largest associations with the presence of functional status impacts were physical functioning and social functioning. Results suggest that the problems/symptoms accompanying UI are associated in a consequential way with functional status. These results were corroborated with the work by Ko et al. (2005) indicating substantial SF-36 impacts on the PCS and MCS scores cross-sectionally in a Medicare Advantage sample.

In contrast, interventions designed to impact UI have been shown to have small impacts on functional status. In a randomized clinical trial study examining the comparative efficacy of behavioral interventions using bladder training, pelvic muscle exercise and combination therapy, results indicated that there were fewer incontinence events and those with stress incontinence exhibited greater improvement in health related quality of life using a disease specific measure. Corcoles et al. (2009), in a quasi-experimental pretest post-test single arm intervention, assessed the effects of incontinence surgery (transvaginal sling techniques with the most common approach being urethropexy with transobturator tape followed by urethropexy with bone anchoring using In-Fast sling and tension-free vaginal tape) on functional status using the Kings Health Questionnaire, a disease specific assessment of functional status. Improvements were marked and significant for impact on incontinence in the subjects' life for SF-36 scales, physical limitations, role limitations and social limitations. Results showed improvements in the small to moderate range. Clinical variables most closely associated with improvements included longer interval between daytime micturitions (>120 min), no evidence of urinary leakage and no post-operative complications. In another randomized controlled trial of the efficacy of extended release Tolterodine (a competitive muscarinic receptor antagonist for the treatment of overactive bladder), Kelleher et al. (2002) used the SF-36 as one of the endpoints and found positive differences for physical and mental summaries that were less than 10% of a standard deviation. Finally, a comprehensive literature review of the impacts of interventions on health related quality of life on community dwelling males and females for behavioral and other clinical interventions report small improvements when the SF-36 is used as endpoints in these studies (Prevention of Fecal and Urinary Incontinence by the Minnesota Evidence-based Practice Center

#161 (2007). Overall, the impact of clinical interventions on physical and mental functioning is small at best. Multi-component interventions that combine more than one modality are likely to yield stronger effects on functional status outcomes as they may increase the likelihood of alleviation of symptoms that often accompany UI and are strongly related to physical and psychological status.

B. Exercise or Physical Activity

Exercise and physical activity have long been known to have positive effects on functional status and health outcomes. The HOS survey includes items related to whether your doctor or health care provider has spoken with you about exercise or physical activity in the past 12 months and if yes did the provider give advice on starting, increasing or maintaining levels of exercise or physical activity. The rationale for inclusion of such items in the HOS is that there is much evidence that structured programs, especially for the elderly, can have important health benefits and improve or even reverse physical and mental functional decline in the elderly. This has also been shown in elderly patients that are compromised with chronic disease conditions such as those with heart disease, COPD and depression. The American College of Sports Medicine and the American Heart Association issued recommendations on the types and intensities of physical activities in older adults (Nelson et al., 2007) and made recommendations emphasizing "moderate-intensity aerobic activity, muscle strengthening activity, reducing sedentary behavior and risk management." The literature suggests that such recommendations as these can have small to moderate effects on the physical and mental functioning of the elderly.

In an important study, Kelly et al. (2009) conducted a meta-analysis to examine the impact of exercise and health related quality of life in older community based adults. The study included 11 randomized clinical trials (RCT) that included 617 men and women. Physical activity intervention arms for the clinical trials included strength training, aerobic training with some that participated in both types of activities. The SF-36 PCS was the principal outcome in these RCT's. Results indicated that physical activity demonstrated statistically significant increases in physical functioning in the small to moderate range of effects. Odds ratio of 2.14 (95% CI; 1.42-3.24) was interpreted as an odds of improving in physical functioning more than 2 times greater with a physical activity intervention compared with the odds in a control group without physical activity. These differences were deemed clinically relevant, the paper also points out that the integration of combined strategies such as strength and aerobic exercise can have a larger effect.

In several separate studies regarding exercise programs, results reported small to moderate effects with exercise programs on functional status. Bize et al. (2007), in a systematic review of physical activity levels and SF-36 outcomes in general community populations of adults, reported on the basis of 14 studies with positive relationships between self-reported physical activity and measures of functional status and wellbeing. Differences in scores for the PCS component summary was in the small to moderate range for these studies. Cohort studies were in the small range of positive effects.

Individual studies in the literature give a range of interventions regarding exercise and physical activity. Courtney et al. (2009) used the SF-12 v.2 in a randomized clinical trial of the elderly to examine the effects of an innovative model of discharge planning and in-home exercise training

follow-up care using "a comprehensive nursing and physiotherapy assessment and individualized program of exercise strategies and nurse conducted home visit and telephone follow-up." The results of this study reported on those 65 years of age and older with significant effects for the differences between the intervention and control groups (moderate effects for PCS and small for MCS). The PCS differences were in the moderate range and were robust as they did not differ by much for diagnostic groups including cardiac disease, respiratory disease, and gastro-intestinal disease. The authors also indicate significantly less emergency hospital readmissions in the intervention group.

In another intervention study, Lawton et al. (2008) designed a single blinded randomized trial of 1089 sedentary women and examined the impact of clinician counseling on physical activity using 'exercise prescriptions' by the provider at 12 and 24 months. Evidence suggested impacts on increased physical activity and positive functional status using the SF-36 as the endpoints. Effects were larger at 12 months than 24 months, although significant for physical function, role limitations due to physical problems and mental health. Positive effects were in the small to moderate range. The authors concluded that exercise programs can produce "sustained positive increases" in physical activity and, with a combination of other interventions such as face to face sessions at follow-up and monthly telephone contacts, might increase the effects observed. In yet another similar study, Elley et al. (2003) reported on a cluster randomized controlled trial using patients to prompt their general practitioner or nurse provider to deliver a "green prescription." This entails 4 hours of training in the use of motivational interviewing techniques. Those subjects identified as more sedentary receive a prompt card and the provider discusses with the patient increasing home based physical activity through "goal setting." These goals are then written on a green prescription that is provided to the patient. Results showed positive changes in the SF-36 scores compared to the control group. Significant positive changes were reported for role limitations due to physical problems, bodily pain, general health and vitality. Positive effects for the intervention were in the small and moderate ranges. These studies suggest that a low cost intervention can be implemented with positive effects on physical and mental functioning that can slow the progression of decline in functional outcomes or in some cases reverse it.

To summarize, results of this body of literature related to physical activity suggest strong to moderate positive relationships between physical activity and physical functioning, as well as mental functioning. Interventions that combine different strategies, such as counseling and aerobic or other structured physical activities, are more effective in impacting functional outcomes. In addition, impacts are more dramatic in elderly and frail patients who are sedentary and who might benefit more from these structured interventions.

C. Fall Risk Management

It has been estimated that about 30% of community elders fall each year (Gillespie et al., 2009). Falls can be a life changing event for the elderly with obvious implications for sudden loss of functional abilities and co-occurring impacts on physical and mental functioning. Impacts have been as dramatic as 10 points lower on the physical summary (PCS) and 5 points lower on mental summary (MCS), about 1 standard deviation lower for physical and 50% of one standard deviation lower for mental functioning, respectively, compared with baseline prior to the fall. Four items in the HOS are related to falls, including history of falls in the past 12 months,

problems with balance or walking and if the doctor or provider has intervened to help to prevent falls. In an important systematic review of the literature for the U.S. Preventive Task force by Michael et al. (2010), 638 articles were identified with randomized controlled trial designs. Sixteen studies were deemed of fair quality and evaluated for exercise or physical therapy and its impact on the risk of falling with a protective effect risk ratio of 0.87, (95% CI 0.81 to 0.94). Nine other studies on vitamin D supplementation give a risk ratio of 0.83 (95% CI 0.77 to 0.89). Other trials evaluated by the task force included vision correction using cataract surgery and vision screening and referral. Separately and importantly, studies of home-hazard modification that include in home assessments with modifications such as "non-slip tape put on rugs especially on steps" and the addition of safety devices such as bars on the toilet and bathtub, reduced risk falling with a range from 7% to 41%, although significance of these studies was limited to one article (Campbell et al.. 2005). The systematic review concludes that exercise programs are effective in reducing falls. In another important review of the 'fall' literature, Gillespie et al. (2009) conducted a Cochrane systematic review and included 111 trials using Cochrane criteria for selection of studies. The results suggest that several intervention types reduced the risk of falling: multiple component group exercise, relative risk (RR) 0.83, (95% CI 0.72 to 0.97), Tai Chi, RR 0.65, (95% CI 0.51-0.82), and individually prescribed multiple-component home based exercise programs RR 0.77, (95% CI 0.61-0.97). Home safety interventions were useful in a subgroup of elderly with visual impairments and in others who were at high risk of falls.

We infer from these results that successful fall reduction will have a positive impact on functional status in the elderly.

D. Osteoporosis in Older Women

Estimates of osteoporosis in the US population indicate that as many as 50% over the age of 50 will be at risk for osteoporosis during their life time. The proportion is greater for women than for men and rates are highest in white women. Osteoporosis related fractures have important consequences for the decline in functional status in the elderly. The use of screening for assessing osteoporosis is important in order to consider intervention strategies to avert falls and the effects of osteoporosis in elderly women who might be at greater risk of falls and fractures. The HOS includes an item related to osteoporosis in women that asks if the subject has ever had a bone density test to check for osteoporosis. Based upon an updated review of evidence on osteoporosis screening, Nelson et al. (2010) examined the effectiveness and deleterious effects of osteoporosis screening in reducing fractures for men and post-menopausal women with no previous history of fractures. There were no studies identified that examined the effectiveness of screening and evaluating potential harms from screening. Studies have reported the performance of risk assessment instruments to stratify subjects into risk of osteoporosis categories. Instruments are modest at best as predictors of low bone density (area under the ROC curve, 0.13 to 0.87; 14 instruments) and fractures (area under the ROC curve, 0.48 to 0.89). The recommendations from the U.S. Preventive Services Task Force is that women age 65 and older be screened routinely for osteoporosis with a recommendation grade of B (i.e., there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.). It is therefore recommended as well as clinically sensible that

screening be conducted in elderly women. However, further research is needed to fully appreciate the overall effectiveness of osteoporosis screening.

VI. Literature Review Summary

The following literature review was designed to be comprehensive and relevant to understanding the range of clinical, social and behavioral interventions reported in the literature using the SF and VR measures to assess impacts on HRQoL.

A. Methods

This comprehensive review started with searches in well-known medical search engines that included PubMed/Medline, Cochrane Library of Trials, EMBASE, and CINAHL for each SF and VR survey (SF-12, SF-36, VR-12, and VR-36) using a variety of different names to see the volume of articles yielded. A random sample of articles gave comparable results in PubMed as the other search engines combined, so PubMed was chosen as the database of choice for this literature review. Additionally, it was determined that search results were not case sensitive, as searching for "sf-12" or "SF-12" would generate the same results. The search initially yielded over 10,000 articles for the SF-36 and other SF/VR measures from 1992-2010, we further narrowed the results by searching for each survey and key health terms that reflected what each survey was measuring. We further narrowed the search for articles in English, and for the years 2000-2010. We also included articles using any of the key terms (e.g. health status, patient reported outcomes, health related quality of life, and Medicare), as well as one of fourteen therapeutic clinical areas and two intervention types that include social and behavioral. Results yielded 1218 articles. Abstracts for each of the 1,218 articles were identified and divided among five reviewers (at random, using Excel to randomize and evenly split the ID for each article (PMIDs). Word documents containing the abstracts and excel files with the PMIDs and room for a score were added to the program.

"Excel" was used and programmed to develop a front end user friendly set of fields with drop down menus for purposes of standard data collection of the key relevant elements of each article reviewed. These elements included: therapeutic area, condition(s), age range of subjects, study design, intervention description, instrument used (SF/VR versions), scales reported (PCS, MCS, any of the 8 subscales), sample sizes reported by group and/or totals, scale scores (baseline, follow-up, change, means, and standard deviation or standard error by group). The Excel program was tested and checked for feasibility and use. Raters were trained in the use of the data abstraction approaches for each of the data elements and a common set of 12 articles were reviewed independently by more than one rater and results compared. Results yielded agreement more than 90% of the time.

Not all articles were included in the final set to be reviewed. Articles that were initially identified were further reviewed using the published abstract on the basis of the following inclusion/exclusion criteria. Inclusion criteria are: (1) evaluation of a clinical or social/behavioral intervention, (2) metrics used for evaluation include an SF measure (SF-36, SF-12, VR-36, VR-

12 measures), (3) longitudinal cohort study with at least a baseline and follow-up assessment using the SF metric, and; (4) quantitative empiric data presented in publication of the SF endpoints before and after. Exclusion criteria include: (1) no clinical or social behavioral intervention reported and study is purely descriptive, (2) metrics used to evaluate outcomes do not include an SF measure (SF-36, SF-12, VR-36, VR-12 measures), (3) cross-sectional study with associations on the basis of a single point in time (study does not include repeated measures with at least a baseline and follow-up assessment using the SF metrics), (4) case study that involves "an N of 1" study or very few subjects and is purely qualitative, and; (5) study is purely descriptive involving a discussion of a proposed future study or a current study that is underway with no data reported.

On the basis of the inclusion/exclusion criteria there were 464 articles that remained. These articles were randomly assigned to the 5 reviewers who were given the complete published article on the web server for review. There were an additional 209 articles rejected that left 255 articles for comprehensive review.

Two hundred fifty-five (255) articles were reviewed independently by each of the 5 raters (55 articles per rater) and entered into the Excel data base. Data was output to a SAS file for analysis. Categorical variables were coded and interval scaled variables for the relative effects of interventions were coded for each of the effects at baseline and follow-up measures available for a published study. The physical and mental summary scores (PCS and MCS) were used as the basis for computing effects of the intervention. Many studies reported the subscales of the SF-36 without reporting the PCS and MCS scores. We calculated a predicted (Y hat) score on the basis of the 8 subscales when they were reported. The equation for computing PCS and MCS from the SF-36 is taken from the SF-36 Users Manual (Ware et al., 2005. SF-36 Physical & Mental Health Summary Scales: A Manual for Users of Version 1). This equation is based upon a T-score transformation and standardized to a 50 based upon a 1998 norm of the U.S. population with a norm of 50 and a standard deviation set to 10 units, higher scores denote better health. We have chosen this formula as 90% of the articles reported use of the SF-36 version 1.

PCS MCS Norm 98 are calculated with formula:

PCS = 0.177876*pf + 0.0993503*rp + 0.1359734*bp + 0.1168313*gh +
0.0136178*vt - 0.00327*sf - 0.0606988*re - 0.1253423*mh + 23.72968;

MCS = -0.0964806*pf - 0.0348783*rp - 0.041669*bp - 0.0073552*gh +
0.1113942*vt + 0.1167122*sf + 0.1371838*re + 0.275919*mh + 15.90774;

For PCS and MCS:

Effect sized for a single arm study is calculated as:

Change in the baseline and follow-up divided by 10 (approximate standard deviation for PCS and MCS); for two arm studies, we compute PCS and MCS taking the change of the change for each arm and dividing this by 10 to yield a single effect. For three and four arm studies we compute an effect size for each of the interventions compared with the placebo or usual care group giving 2 and 3 effect sizes, respectively.

If standard errors are not reported for an effect size, we compute the standard error for simple random samples on the basis of the assumed standard deviation using the sample sizes and mean values reported using garden variety formulas:

Sample mean, x $SE_x = sd / sqrt(n)$

Difference between means, $x_1 - x_2$ $SE_{x1-x2} = sqrt [s^2_1 / n_1 + s^2_2 / n_2]$

On the basis of the standard error, we report the significance using the simple T statistic (T >= 1.96, or T <= -1.96) for significance at the P=0.05 level for the effect size difference between pre and post intervention compared with the placebo or usual care groups.

B. Summary

Tables 1-3 gives a summary of information from the data base from the comprehensive review of the 255 articles. Average age across these articles was 56 years of age with a range from 28 to 87. Close to 89% of the articles included both men and women, with about 4% men only and 8% women only. The largest fraction of articles about 41% were an observational cohort study involving one arm studies, close to 30% were randomized clinical trials without placebo but with a comparison group that generally was usual care. About 15% were at least a two-arm study involving a non-randomized comparative trial without a placebo, but with a usual care group. The most common therapeutic areas specifically identified included musculoskeletal/orthopedic (20%) followed by respiratory disorders (11%), psychiatric (10%), and cardiovascular (9%). The most prevalent interventions were surgery (24%), medications (16%) and physical therapy (15%). Close to 19% of the studies reported a non-specific intervention generally involving a single arm study that followed usual care over time in a specific diagnostic category. Tables 3 and 4 give the frequencies of multiple therapeutic areas and interventions reported among the 255 published articles.

Table 4 gives the comprehensive listing of individual studies grouped by therapeutic area. Included is the average age reported, the condition that is the focus of the study, the average age reported for the sample of a study, the survey short form instrument that forms the endpoints for the study, the study design, the treatment or intervention, the difference in the scores reported for PCS and MCS, the relative effect size, T statistic and significance. The table provides specifics for each of the 255 studies comprehensively reviewed. This table forms an important reference for purposes of gauging the relative effects of specific interventions given the intervention described in the published article. Each of the studies reported within a therapeutic area gives a range of effect sizes for PCS and MCS that are predominately small and moderate with few in the large range.

Table 5 gives examples of those studies that report small, moderate and large effects. This table provides a specific illustration of the interpretation of the effects of interventions for those studies deemed highly credible. For PCS and MCS, we define small effects in the range of 0.20 to 0.40 (20% to 40% of one standard deviation change), moderate effects 0.50 to 0.70 (50% to 70% of one standard deviation change) and large effects >= 0.80 (80% of one standard deviation or larger). This table shows the health effects of chronic conditions and change in health from specific interventions by effect size categories. The following studies included samples with conditions and associated interventions that met the small effect size criterion (0.20 to 0.40) for change in PCS scores: back pain/sciatica, angina, type II diabetes, past myocardial infarction, chronic lung disease and irritable bowel syndrome. Osteoarthritis, duodenal ulcer and limitations in use of arm and leg met the moderate effect size criterion (0.50 to 0.70) for change in PCS scores. Severe cases of congestive heart failure and rheumatoid arthritis met the large effect size criterion (0.80 and greater) for changes in PCS scores. Chronic lung disease and vision

impairment met the small effect size criterion (0.2 to 0.4) for change in MCS scores. Asthma met the moderate effect size criterion (0.5 to 0.7) for change in MCS scores. Depression met the large effect size criterion (0.8 and greater) for change in MCS scores.

Social and behavioral interventions met the effect size criterion as small (0.2 to 0.4) to moderate (0.5 to 0.7) for change in PCS scores and small to large (0.8 and greater) for change in MCS scores. Tamari (2009) showed that the quality of life improved in a community-dwelling elderly population with mild disability who undertook a three-month group-based progressive resistance exercise program. This study met the small size criterion for change in PCS scores; however the study met the moderate effect size criterion for change in MCS scores. Marchesini et al. (2002) showed the positive effects of cognitive-behavioral therapy, mainly in subjects with binge eating. This study met the small size criterion for change in PCS and MCS scores. Mindfulness-based stress reduction vs. usual care (Plews-Ogan et al., 2005) met the moderate effect size criterion for change in MCS scores. McHugh et al. (2001) evaluated the effectiveness of a nurse led shared care program to improve coronary heart disease risk factor levels and general health status and to reduce anxiety and depression in patients waiting coronary artery bypass grafting. This study met the large effect size criterion for change in MCS scores.

Medication therapy met the effect size criterion at the moderate level (0.5 to 0.7) for change in PCS scores and small (0.2 to 0.4) to large (0.8 and greater) for change in MCS scores. Kulig et al. (2003) showed that gastroesophageal reflux causes a significant impairment in the quality of life, which can be attenuated or normalized within a time period as short as 2 weeks by treatment with esomeprazole. This study met the moderate size criterion for change in PCS scores. Croghan et al. (2005) reported that smokers treated for nicotine dependence who stop smoking for a year report more improvement in-quality-of-life compared with those who continue to smoke. This study met the moderate effect size for change in PCS scores. The use of Adalimumab vs. placebo (Davis Jr. et al., 2007) met the moderate size criterion for change in PCS scores. The use of Escitalopram for depression and alcoholism (Kroenke et al., 2001) reported a moderate effect size for change in MCS scores. The use of Escitalopram in patients with hepatitis C (Gleason et al., 2005) met the large effect size criterion for change in MCS scores.

Surgical interventions indicate a range of effect sizes (from small (0.2 to 0.4) to large (0.8 and greater)) for change in PCS and MCS scores. The following surgical interventions met the small effect size criterion for change in PCS and/or MCS scores: peripheral endovascular revascularization (Safley et al., 2007) and surgery for prostate cancer vs. radiation therapy (Hu et al., 2006). Ablation of atrial fibrillation (Berkowitsch et al., 2003) produced a moderate effect size for change in PCS scores and the large effect size criterion for change in MCS scores. Total hip replacement (Beaupre et al., 2001) and lumbar spine surgery met the large effect size criterion for change in PCS scores and the moderate effect size criterion for change in MCS

scores. Coronary arterial bypass grafting intervention resulted in large effect sizes for change in PCS and MCS scores.

Results suggest that focused medication and surgical interventions include studies with a range from small to large effects on PCS and MCS. Studies that combine both behavioral and medical/mental health interventions have larger impacts in the moderate to large range of effect sizes when juxtaposed with those interventions that use single interventions.

VII. Conclusions and Recommendations

This literature review gives an overview of selected intervention studies that have shown impacts on the course of functional status in the elderly. We have focused on those interventions for which there is some evidence that they can impact positively the expected decline in elderly patients 65 years of age and older. The slowing of this functional decline or in some cases their reversal is important to consider as the administrators and managers of plans decide on how to direct their resources for purposes of clinical and socially based interventions. Consistent in much of the literature reviewed is the use of single interventions directed in the ambulatory care setting and the home. Single interventions across many different studies impact functional status with small positive effects. The use of bundled multi-component interventions that combine medical including surgery and pharmacological interventions with mental health/social and behavioral interventions often give bigger effects in the moderate to large range. Interventions that occur over larger time windows that are sustained with re-enforcement give more striking impacts. The use of the "chronic care model" as one basis for implementing interventions can consider a focus on behavioral counseling, exercise and medication monitoring so that clinical impacts on functional decline can be realized, especially if they are provided for the more vulnerable populations of frail elders.

Table 1: Summary Statistics for Published Articles

			Frequency	Percent
Age				
	N	199		
	Mean	56		
	Median	57.1		
	Standard Deviation	12.3		
	Minimum	28		
	Maximum	87		
Gender[1]				
	Women Only		18	7.6
	Men Only		9	3.8
	Both Women and Men		211	88.7
Frequency of Study Design[2]				
	Case-Control		6	2.4
	Non-randomized, comparative trial (no placebo)		39	15.3
	Observational/Cohort Study (one arm only)		105	41.2
	Randomized, comparative trial (no placebo)		77	30.2
	Randomized, placebo-controlled cross-over trial		3	1.2
	Randomized, placebo-controlled trial		22	8.6
	Multiple Study Designs		1	0.4
Therapeutic Area[3]				
	Cardiovascular		23	9.2
	Exercise		7	2.8
	Gastrointestinal Disorders		6	2.4
	Genital-Urinary Disorders		15	6.0
	Geriatric Studies		5	2.0
	Musculoskeletal/Orthopedics		50	20.0
	Neurology		11	4.4
	Nutritional		5	2.0
	Other		26	10.4
	Psychiatric Disorders		25	10.0
	Renal		9	3.6
	Respiratory Disorders		27	10.8
	Surgical		19	7.6
	Multiple		14	5.6
	None specifically identified		7	2.8

Table 1: Summary Statistics for Published Articles (continued)

			Frequency	Percent
Intervention[4]				
	Dialysis		4	1.6
	Diet		2	0.8
	Informational		3	1.2
	Medication(s)		38	16.0
	Physical Therapy		35	14.7
	Psychotherapy		4	1.7
	Social/Behavioral		15	6.3
	Surgery		58	24.4
	Multiple		34	14.3
	Non-Specific		45	18.9

[1]Missing data for age: Frequency =56, and gender: Frequency = 17.

[2]Missing data for frequency of study design: Frequency = 2.

[3]Missing data for therapeutic area: Frequency = 6.

[4]Missing data for intervention: Frequency = 17.

Table 2: Multiple Therapeutic Areas

Therapeutic Areas	Frequency	Percent of Total*
Musculoskeletal and Surgical	3	1.21
Surgical and Other	2	0.81
Neurology and Musculoskeletal	2	0.81
Exercise and Other	1	0.4
Musculoskeletal and Psychiatric	1	0.4
Genital-Urinary, Neurology, and Musculoskeletal	1	0.4
Cardiovascular and Exercise	1	0.4
Cardiovascular and Genital-Urinary	1	0.4
None and Exercise	1	0.4
None and Psychiatric	1	0.4

*Percent of total of all therapeutic areas selected.

Table 3: Multiple Interventions

Interventions	Frequency	Percent of Total*
Medication(s) and Surgery	8	3.43
Informational and Social/Behavioral	7	3.00
Surgery and Physical Therapy	3	1.29
Medication(s) and Physical Therapy	3	1.29
None and Surgery	3	1.29
Psychotherapy and Social/Behavioral	1	0.43
Occupational Therapy and Psychotherapy	1	0.43
Physical Therapy and Social/Behavioral	1	0.43
Physical Therapy and Informational	1	0.43
Physical Therapy and Diet	1	0.43
Medication(s) and Occupational Therapy	1	0.43
Diet, Informational, and Social/Behavioral	1	0.43
Physical Therapy, Diet, and Informational	1	0.43
Medication(s), Diet and Informational	1	0.43
Medication(s), Physical Therapy, Psychotherapy, Informational, Social/Behavioral	1	0.43

*Percent of total of all therapeutic areas selected.

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Table 4: Summary of PCS and MCS Change Scores

Therapeutic Area	Condition	Treatments	PCS Change Difference	PCS Change Effect Size	PCS Change T[1]	PCS Change Sign[2]	MCS Change Difference	MCS Change Effect Size	MCS Change T[1]	MCS Change Sign[2]	Average Age	Study Design	Citation
Cardiovascular	Atrial fibrillation	Ablation of atrial fibrillation	5.30	0.53	Inc	Inc	9.33	0.93	Inc	Inc	58	Non-randomized, comparative trial (no placebo)	Berkowitsch, A 2003
	Cardiac problems such as bradycardia, syncope and heart failure requiring pace maker	VVI®	-1.51				2.76				76	Randomized, comparative trial (no placebo)	Gribbin, GM 2004
		Atrial based	1.40				0.66						
		VVI® vs. Atrial based		-0.29	Inc	Inc		0.21	Inc	Inc			
	Cardiac surgical patients	Coronary bypass grafting	6.91	0.69	0.72	NS	5.38	0.54	0.56	NS	63	Observational/ Cohort study (no intervention)	Myles, PS 2001
	Congestive heart failure	Cardiac resynchronization therapy	-0.29	-0.03	-1.33	NS	2.94	0.29	0.13	NS	68	Non-randomized, comparative trial (no placebo)	Hoth, KF 2008
		Transcendental Meditation ™	0.25				-6.41				64.5	Randomized, comparative trial (no placebo)	Jayadevappa , R 2007
		health education (HE)	3.21				-1.07						
		Transcendental Meditation ™ vs. health education (HE)		-0.30	-7.05	NS		-0.53	-0.13	NS			
		Normal weight	-0.02								78	Observational/ Cohort study (no intervention)	Prince, SA 2008
		Overweight	1.40										
		Obese	-0.30										
		Normal weight vs. Overweight		-0.14	Inc	Inc							
		Normal weight vs. Obese		0.03	Inc	Inc							
	Coronary artery disease	Coronary artery bypass grafting	8.80	0.88	Inc	Inc	3.80	0.38	Inc	Inc	66	Observational/ Cohort study (no intervention)	Le Grande, MR 2006
		Cardiac rehabilitation	1.86				0.60				69.5	Randomized, comparative trial (no placebo)	Seki, E 2003
		Control	0.46				-8.93						
		Cardiac rehabilitation vs. Control		0.14	4.31	NS		0.95	0.29	NS			
		Post coronary artery bypass grafting	-0.33	-0.03	-3.67	NS	3.86	0.39	0.43	NS		Observational/ Cohort study (no intervention)	Mayer, C 2003
		Health education by a nurse	-0.94				7.89				62	Randomized, comparative trial (no placebo)	McHugh, F 2001
		Usual care	0.15				-7.04						
		Health education by a nurse vs. usual care		-0.11	-5.37	NS		1.49	0.74	NS			
	Coronary artery disease and congestive heart failure	Coronary artery disease (CAD)	2.14				0.69				70	Observational/ Cohort study (no intervention)	Spiraki, C 2008
		Congestive heart failure (CHF)	1.41				0.31						
		CAD vs. CHF		0.07	4.23	NS		0.04	2.20	NS			

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	Coronary bypass graft	On pump	10.17				4.03				60	Randomized, comparative trial (no placebo)	Nogueira, CR 2008
		Off pump	9.33				5.65						
		On pump vs. off pump		0.08	5.96	NS		-0.16	-0.12	NS			
	Coronary heart disease	Intervention	-0.46				-0.36				69	Randomized, comparative trial (no placebo)	Community Pharmacy Medicines Management Project Evaluation Team 2007
		Control	-0.41				1.19						
		Intervention vs. control		-0.01	-8.63	NS		-0.15	-0.24	NS			
		CABG SF-36	7.00								60	Observational/ Cohort study (no intervention)	Müller-Nordhorn, J 2004
		CABG SF-12	8.00										
		PTCA SF-36	5.00										
		PTCA SF-12	4.00										
		CABG SF-36 vs. CABG SF-12		-0.10	Inc	Inc							
		CABG SF-36 vs. PTCA SF-36		0.20	Inc	Inc							
		CABG SF-36 vs. PTCA SF-12		0.30	Inc	Inc							
	Myocardial infarction	Supervised outpatient cardiac rehabilitation	2.64	0.26	0.24	NS	0.71	0.07	6.42	NS	62	Non-randomized, comparative trial (no placebo)	Izawa, K 2004
	Multivessel coronary artery disease	Surgery	8.30				6.40				63.5	Non-randomized, comparative trial (no placebo)	Krecki, R 2010
		Medication	1.90				3.50						
		Surgery vs. medication		0.64	0.33	NS		0.29	0.15	NS			
	Peripheral arterial disease	Peripheral Endovascular Revascularization	3.00	0.30	0.43	NS	0.00	0.00	0	NS	68	Observational/ Cohort study (no intervention)	Safley, DM 2007
Exercise	Healthy individuals	Yoga	1.20				2.20				71.67	Randomized, comparative trial (no placebo)	Oken, BS 2006
		Exercise	-2.10				-0.40						
		Wait list	-2.10				1.70						
		Yoga vs. exercise		0.33	0.16	NS		0.26	0.12	NS			
		Yoga vs. wait list		0.33	0.15	NS		0.05	2.35	NS			
	Knee or hip arthroplasty	OMT treatment	-2.45				9.75				69	Randomized, comparative trial (no placebo)	Licciardone, JC 2004
		Sham treatment	-3.03				6.67						
		OMT treatment vs. Sham treatment		0.06	2.25	NS		0.31	0.12	NS			
	Obesity	Control	0.72				-2.30				70	Randomized, comparative trial (no placebo)	Villareal, DT 2006
		Exercise program	10.14				0.13						
		Control vs. exercise program		-0.94	-0.24	NS		-0.24	-6.11	NS			
	Risk of hospital readmission	Exercise program	11.20				13.20				78.5	Randomized, comparative trial (no placebo)	Courtney, M 2009
		Control	-8.50				1.90						
		Control vs. exercise program		1.97	1.09	NS		1.13	0.62	NS			
	Sedentary physical activity	Exercise program	2.60				1.41				58	Randomized, comparative trial (no placebo)	Elley, CR 2003
		Control	0.71				1.49						
		Control vs. exercise program		0.19	0.28	NS		-0.01	-1.10	NS			
Gastrointestinal	Diabetic	Gastric Electrical	9.70	0.97	0.67	NS	9.10	0.91	0.63	NS	38	Observational/	Lin, Z 2004

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disorders	gastroparesis	Stimulation										Cohort study (no intervention)	
	Dyspepsia	GP (control)	-37.20								49	Randomized, comparative trial (no placebo)	Chan, D 2009
		CNP (intervention)	127.50										
		GP (control) vs. GNP (intervention)		-16.47	Inc	Inc							
	Gastroesophageal reflux	Esomeprazole	5.80	0.58	Inc	Inc	5.30	0.53	Inc	Inc	54	Non-randomized, comparative trial (no placebo)	Kulig, M 2003
	Hepatitis C	Escitalopram	1.88	0.19	7.97	NS	15.91	1.59	0.68	NS	45	Observational/ Cohort study (no intervention)	Gleason, OC 2005
Genital-Urinary Disorders	PCOS	Electrocautery	-3.41				0.28				28.5	Randomized, comparative trial (no placebo)	van, Wely M 2004
		rFSH	-3.34				-2.09						
		Electrocautery vs. rFSH		-0.01	-4.27	NS		0.24	0.15	NS			
	Post-natal QoL after normal delivery vs. Cesarean section	Normal delivery	4.14				-0.33				25	Non-randomized, comparative trial (no placebo)	Torkan, B 2009
		Cesarean section	1.19				5.38						
		Normal delivery vs. Cesarean section		0.29	0.15	NS		-0.57	-0.29	NS			
	Prostate cancer	Surgery	-0.78				0.83					Non-randomized, comparative trial (no placebo)	Hu, JC 2006
		Salvage RT	-1.67				0.06						
		Primary RT	-3.24				-1.88						
		Surgery vs. Salvage RT		0.09	7.19	NS		0.08	6.22	NS			
		Surgery vs. Primary RT		0.25	0.18	NS		0.27	0.20	NS			
		Whites	1.51				-0.25				70	Observational/ Cohort study (no intervention)	Jayadevappa , R 2007
		African American	2.77				1.69						
		Whites vs. African American		-0.13	-8.69	NS		-0.19	-0.13	NS			
		No intervention	-2.14	-0.21	-1.15	NS	2.07	0.21	1.11	NS		Observational/ Cohort study (no intervention)	Sadetsky, N 2009
		No intervention	-2.30	-0.23	-0.17	NS	-0.90	-0.09	-6.61	NS		Observational/ Cohort study (no intervention)	Staff, I 2003
	Prostate cancer (early stage)	Radical prostatectomy	-1.00				2.00				66.33	Observational/ Cohort study (no intervention)	Litwin, MS 2007
		External beam irradiation	-2.00				1.00						
		Brachytherapy	-3.00				0.00						
		Radical prostatectomy vs. External beam irradiation		0.10	7.89	NS		0.10	7.89	NS			
		Radical prostatectomy vs. Brachytherapy		0.20	0.17	NS		0.20	0.17	NS			
	Prostate cancer patients who underwent radical prostatectomy	Control group	2.68				0.37				60	Randomized, comparative trial (no placebo)	Weber, BA 2007
		Experimental group	2.09				1.08						
		Control group vs. Experimental group		0.06	Inc	Inc		-0.07	Inc	Inc			

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	Symptomatic Uterine Fibroids	Uterine-Artery Embolization	6.36				8.33				44	Randomized, comparative trial (no placebo)	Edwards, RD 2007
		Surgery	8.81				10.07						
		Uterine-Artery Embolization vs. Surgery		-0.24	-0.14	NS		-0.17	-9.77	NS			
	Uterine Fibroids	Overall	5.43	0.54	0.55	NS	7.30	0.73	0.74	NS	45	Observational/ Cohort study (no intervention)	Harding, G 2008
	Uterine disorder	Levonorgestrel releasing intrauterine system	0.86				5.87					Randomized, comparative trial (no placebo)	Hurskainen, R 2004
		Hysterectomy	1.36				5.39						
		Levonorgestrel releasing intrauterine system vs. hysterectomy		-0.05	-3.86	NS		0.05	3.63	NS			
	Uterine disorder	Hysterectomy	7.00				7.00				41.5	Randomized, comparative trial (no placebo)	Kuppermann , M 2004
		Expanded medical treatment	9.00				9.00						
		Hysterectomy vs. Expanded medical treatment		-0.20	-7.94	NS		-0.20	-7.94	NS			
Geriatric Studies	Any hospitalized older male patient	No intervention	1.72	0.17	0.64	NS	1.15	0.11	0.43	NS	74	Observational/ Cohort study (no intervention)	Purser, JL 2005
	Diabetes	Progressive resistance exercise	1.43	0.14	0.11	NS	5.66	0.57	0.45	NS	76	Observational/ Cohort study (no intervention)	Tamari, K 2009
	Elderly	Education	2.90				0.87					Randomized, comparative trial (no placebo)	Pit, SW 2007
		Control	2.90				1.23						
		Education vs. Control		0.00	0.00	NS		-0.04	-4.85	NS			
	Elderly age	Geriatric Eval and Management Unit	5.41				4.07					Randomized, comparative trial (no placebo)	Cohen, HJ 2002
		Usual Care Inpatient	4.08				3.33						
		Geriatric Eval and Management Clinic	4.65				4.89						
		Usual Care Outpatient	4.82				2.56						
		Geriatric Eval and Management Unit vs. Usual Care Inpatient		0.13	0.18	NS		0.07	9.67	NS			
		Geriatric Eval and Management Unit vs. Geriatric Eval and Management Clinic		0.08	0.10	NS		-0.08	-0.11	NS			
		Geriatric Eval and Management Unit vs. Usual Care		0.06	7.85	NS		0.15	0.20	NS			

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		Outpatient											
	Hearing loss	Air conduction hearing aid	-1.54				3.22				55	Observational/ Cohort study (no intervention)	Hol, MK 2004
		Conventional bone conduction hearing aid	-2.42				1.83						
		Air conduction hearing aid vs. conventional bone conduction hearing aid		0.09	3.17	NS		0.14	4.99	NS			
Multiple	Cardiovascular disease in men with prostate cancer	Intervention with No cardiovascular (CV) disease severity	-4.00				1.00				65.75	Observational/ Cohort study (interventions for those with radical prostatectomy or radiotherapy)	van, de Poll-Franse LV 2008
		Intervention with mild CV disease severity	-3.00				0.00						
		Intervention with moderate CV disease severity	-1.00				-1.00						
		Intervention with severe CV disease severity	-1.00				-1.00						
		Intervention with no CV disease severity vs. Intervention with mild CV disease severity		-0.10	-0.09	NS		0.10	0.09	NS			
		Intervention with No CV disease severity vs. Intervention wtih moderate CV disease severity		-0.30	-0.22	NS		0.10	0.07	NS			
		Intervention with No CV disease severity vs. Intervention with severe CV disease severity		-0.30	-0.13	NS		0.20	8.79	NS			
	Changes in cognition and QoL in post-menopausal women on ultra low dose estrogen	Estradiol group	-1.44				-1.46				67	Randomized, placebo-controlled trial	Yaffe, K 2006
		Placebo group	-1.07				-0.05						
		Estradiol group vs. Placebo group		-0.04	Inc	Inc		-0.10	Inc	Inc			
	Critical illness requiring ICU admission: trauma, sepsis, resp, CV	ICU patients	1.61	0.16	0.32	NS	0.21	0.02	0.04	NS	59	Observational/ Cohort study (no intervention)	Orwelius, L 2010
	Generalized dystonia	Deep brain stimulation	22.00	2.20	Inc	Inc						Non-randomized, comparative trial (no placebo)	Kiss, ZH 2007
	Healthy individuals	Control	1.20				0.76				57.5	Randomized, comparative trial (no	Martin, CK 2009
		4 KKW	1.95				3.00						

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		8 KKW	2.28				2.87					placebo)	
		12 KKW	3.37				4.01						
		Control vs. 4 KKW		-0.07	Inc	Inc		-0.22	Inc	Inc			
		Control vs. 8 KKW		-0.11	Inc	Inc		-0.21	Inc	Inc			
		Control vs. 12 KKW		-0.22	Inc	Inc		-0.32	Inc	Inc			
	HIV	Control	1.77				1.73				45.5	Randomized, comparative trial (no placebo)	Cade, WT 2010
		Yoga	-0.67				4.23						
		Control vs. Yoga		0.24	9.36	NS		-0.25	-9.59	NS			
	Multiple Sclerosis	Multiple Sclerosis Medication	0.20	0.02	3.36	NS	2.50	0.25	0.42	NS	53	Observational/ Cohort study (no intervention)	Stockl, KM 2010
	Osteoarthritis of the hip	Cemented	10.03				3.98				69	Non-randomized, comparative trial (no placebo)	Nilsdotter, AK 2003
		Hybrid	12.84				6.63						
		Cemented vs. Hybrid		-0.28	-0.20	NS		-0.26	-0.19	NS			
	Schizophrenia	New antipsychotics	0.90	0.09	0.21	NS	2.60	0.26	0.61	NS	44	Observational/ Cohort study (no intervention)	Fleischhacker, WW 2005
	Sepsis	Severe sepsis	-4.20	-0.42	-0.55	NS	1.00	0.10	0.13	NS	70	Observational/ Cohort study (no intervention)	Hofhuis, JG 2008
	Spondylitis	Ventro-Doraal	17.40				15.34				58.5	Randomized, comparative trial (no placebo)	Linhardt, O 2007
		Ventral	22.76				25.23						
		Ventro-Doraal vs. Ventral		-0.54	-0.12	NS		-0.99	-0.22	NS			
Multiple	Subfoveal choroidal neovascularization	Observation-unilateral	-0.70				1.90					Randomized, comparative trial (no placebo)	Hawkins, BS 2004
		Observation-bilateral	-1.00				3.60						
		Surgery-unilateral	-0.20				2.30						
		S-bilateral	-2.70				5.50						
		Observation-unilateral vs. Observation-bilateral		0.03	1.41	NS		-0.17	-7.98	NS			
		Observation-unilateral vs. surgery-unilateral		-0.05	-3.23	NS		-0.04	-2.58	NS			
		Observation-unilateral vs. S-bilateral		0.20	0.09	NS		-0.36	-0.16	NS			
Musculoskeletal/Orthopedics	Acute minor musculoskeletal injuries	Intervention group	-9.49				-9.04				42.5	Randomized, comparative trial (no placebo)	Ottosson, C 2007
		Control group	-6.07				-11.03						
		Intervention group vs. control group		-0.34	-0.19	NS		0.20	0.11	NS			
	ADL's in older adults	Functional assessment group	-0.80				0.60				86	Randomized, comparative trial (no placebo)	Peri, K 2008
		Control group	-1.20				-0.70						
		Functional assessment group vs. Control group		0.04	2.44	NS		0.13	7.93	NS			
	Ankle fracture	Training program	1.40				3.00				33	Non-randomized, comparative trial (no	Nilsson, GM 2009
		Control	2.70				1.80						

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		Training program vs. Control		-0.13	-6.65	NS		0.12	6.14	NS		placebo)	
	Ankylosing spondylitis	Placebo	1.90				2.40				42.5	Randomized, placebo-controlled trial	Davis, JC Jr 2007
		Adalimumab	7.40				3.60						
		Placebo vs. Adalimumab		-0.55	-0.46	NS		-0.12	-0.10	NS			
	Balance and fall risk, HRQoL, depression status in elderly	Control – combined exercise program group	1.36				2.87				80.5	Non-randomized, comparative trial (no placebo)	Cakar, E 2010
		Study – combined exercise program plus jumping	2.06				2.79						
		Control – combined exercise program group vs. Study – combined exercise program plus jumping		-0.07	-2.85	NS		0.01	2.94	NS			
	Chronic low back pain	Anthroposophic therapy	3.98	0.40	0.52	NS	4.50	0.45	0.59	NS	61	Observational/ Cohort study (no intervention)	Hamre, HJ 2007
	Chronic neck pain	GPR group	9.47				6.95				46.5	Randomized, comparative trial (no placebo)	Cunha, AC 2008
		Conventional stretching group	12.78				8.76						
		GPR group vs. Conventional stretching group		-0.33	-9.23	NS		-0.18	-5.03	NS			
	Chronic tendinosis	Chronic tendinosis	9.87	0.99	0.38	NS	2.42	0.24	9.38	NS	52	Observational/ Cohort study (no intervention)	Yeap, EJ 2009
	Degenerative lumbar spinal stenosis	Group 1 – unilateral laminectomy	8.72				2.00				66	Non-randomized, comparative trial (no placebo)	Cavuşoğlu, H 2007
		Group 2 – unilateral laminotomy	7.95				3.01						
		Group 1 – unilateral laminectomy vs. Group 2 – unilateral laminotomy		0.08	3.85	NS		-0.10	-5.05	NS			
	Fibromyalgia	AE	6.41				2.17				49.75	Randomized, comparative trial (no placebo)	Rooks, DS 2007
		ST	2.43				4.27						
		FSHC	3.04				0.12						
		ST-FSHC	5.89				8.89						
		AE vs. ST		0.40	0.17	NS		-0.21	-8.80	NS			
		AE vs. FSHC		0.34	0.13	NS		0.20	7.99	NS			
		AE vs. ST-FSHC		0.05	2.22	NS		-0.67	-0.29	NS			
	Hip arthritis	Appropriate candidates	12.02				5.27				69	Observational/ Cohort study (no intervention)	Quintana, JM 2006
		Uncertain candidates	11.89				3.74						
		Inappropriate candidates	3.87				2.73						
		Appropriate candidates vs.		0.01	1.48	NS		0.15	0.17	NS			

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		Uncertain candidates											
		Appropriate candidates vs. Inappropriate candidates		0.82	0.50	NS		0.25	0.16	NS			
	Hip osteoarthritis	Poor	11.40								67	Observational/ Cohort study (no intervention)	Johansson, HR 2010
		Intermediate	10.00										
		Good	8.20										
		Poor vs. intermediate		0.14	4.48	NS							
		Poor vs. good		0.32	0.11	NS							
		Total hip replacement	17.53	1.75	3.21	S	12.22	1.22	2.24	S	60	Observational/ Cohort study (no intervention)	Shi, HY 2009
Musculoskeletal/Orthopedics	Neck/back pain, disc herniations, arthritis, tendonitis, capsulitis, carpal tunnel, osteoporosis	MSK disorder	-2.01				0.12				51	Case-control	Roux, CH 2005
		Control	-0.19				0.44						
		MSK disorder vs. Control		-0.18	-0.26	NS		-0.03	-4.64	NS			
	Knee arthritis	Control (exercise only)	7.00				4.00				68.33	Randomized, comparative trial (no placebo)	Beaupré, LA 2001
		Exercise combined with slider board therapy	9.00				3.00						
		Exercise combined with continuous passive motion	6.21				4.17						
		Control (exercise only) vs. Exercise combined with slider board therapy		-0.20	-8.94	NS		0.10	4.47	NS			
		Control (exercise only) vs. Exercise combined with continuous passive motion		0.08	3.54	NS		-0.02	-7.42	NS			
	Low back pain	Acute low back pain (<72 hours duration)	10.42	1.04	1.11	NS	-1.83	-0.18	-0.19	NS	44	Observational/ Cohort study (no intervention)	Coste, J 2004
		Surgery	2.00	0.20	0.27	NS	-0.20	-0.02	-2.65	NS		Non-randomized, comparative trial (no placebo)	Fairbank, J 2005
		Therapy group	4.14				0.14				41	Randomized, comparative trial (no placebo)	Frost, H 2004
		Advice only group	3.57				-1.65						
		Therapy group vs. Advice only group		0.06	4.82	NS		0.18	0.15	NS			
		Intervention	10.18				11.39				44	Randomized, comparative trial (no placebo)	Tavafian, SS 2007
		Control	2.67				2.26						
		Intervention vs. Control		0.75	0.38	NS		0.91	0.46	NS			
	Osteoarthritis	Total hip or knee replacement	8.01	0.80	1.10	NS	4.18	0.42	0.57	NS	69	Observational/ Cohort study (no	Baumann, C 2009

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												intervention)	
Musculoskeletal/Orthopedics		Total hip replacement	10.36				4.77				52.25	Observational/ Cohort study (no intervention)	Busija, L 2008
		Total knee replacement	9.92				1.77						
		Arthroscopic partial meniscectomy	6.27				0.76						
		Anterior cruciate ligament reconstruction	14.33				5.75						
		Total hip replacement vs. Total knee replacement		0.04	3.48	NS		0.30	0.23	NS			
		Total hip replacement vs. Arthroscopic partial meniscectomy		0.41	0.29	NS		0.40	0.28	NS			
		Total hip replacement vs. Anterior cruciate ligament reconstruction		-0.40	-0.26	NS		-0.10	-6.43	NS			
		Patients with osteoarthritis of the knee	2.94	0.29	0.26	NS	5.36	0.54	0.48	NS	66	Observational/ Cohort study (no intervention)	Coleman, S 2008
		Total hip resurfacing	20.00				10.40				50.5	Randomized, comparative trial (no placebo)	Fowble, VA 2009
		Total hip arthroplasty	21.20				17.30						
		Total hip resurfacing vs. Total hip arthroplasty		-0.12	-5.44	NS		-0.69	-0.31	NS			
		Hydrotherapy	3.80				1.20				70.33	Randomized, comparative trial (no placebo)	Fransen, M 2007
		Tai chi	2.00				0.00						
		Control	-0.10				0.30						
		Hydrotherapy vs. Tai chi		0.18	9.48	NS		0.12	6.32	NS			
		Hydrotherapy vs. Control		0.39	0.19	NS		0.09	4.36	NS			
		Intervention (revision)	8.80				3.30					Observational/ Cohort study (no intervention)	Hartley, RC 2002
		Intervention (primary)	6.20				-1.30						
		Intervention (revision) vs. Intervention (primary)		0.26	0.16	NS		0.46	0.28	NS			
		Bilateral total knee arthroplasty	28.91	2.89	2.04	S	19.81	1.98	1.40	NS		Observational/ Cohort study (no intervention)	Kilic, E 2009
		Total hip	12.95	1.29	1.65	NS	7.07	0.71	0.90	NS	71	Observational/	Nilsdotter,

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		replacement										Cohort study (no intervention)	AK 2001
		Total hip replacement	7.78	0.78	1.15	NS	4.75	0.47	0.70	NS	70.75	Observational/ Cohort study (no intervention)	Nilsdotter, AK 2010
		Osteoarthritis	2.10	0.21	0.24	NS	-1.10	-0.11	-0.12	NS	64	Observational/ Cohort study (no intervention)	Weigl, M 2004
Musculoskeletal/Orthopedics	Osteoarthritis of hip and knee	Hip arthroplasty <80	12.00				6.00				76.25	Non-randomized, comparative trial (no placebo)	Jones, CA 2001
		Hip arthroplasty =/> 80	13.00				1.00						
		Knee arthroplasty <80	9.00				3.00						
		Knee arthroplasty =/>80	7.00				0.00						
		Hip arthroplasty <80 vs. Hip arthroplasty =/> 80		-0.10	-5.30	NS		0.50	0.27	NS			
		Hip arthroplasty <80 vs. Knee arthroplasty <80		0.30	0.29	NS		0.30	0.29	NS			
		Hip arthroplasty <80 vs. Knee arthroplasty =/>80		0.50	0.27	NS		0.60	0.32	NS			
	Proximal humerus fracture	Female	6.74				2.18				55	Non-randomized, comparative trial (no placebo)	Kirchhoff, C 2008
		Male	6.90				2.85						
		Female vs. Male		-0.02	-6.01	NS		-0.07	-2.56	NS			
	Rheumatoid arthritis	Leflunomide	10.80				4.65				54	Randomized, comparative trial (no placebo)	Cohen, S 2001
		Methotrexate	8.37				2.67						
		Leflunomide vs. Methotrexate		0.24	0.17	NS		0.20	0.14	NS			
	Rheumatoid arthritis and ankylosing spondylitis	RA	6.40				2.71				47.5	Observational/ Cohort study (no intervention)	Heiberg, MS 2005
		AS	8.31				5.11						
		RA vs. AS		-0.19	-0.15	NS		-0.24	-0.18	NS			
	Spinal surgery	Posterior lumbar spine surgery	8.51	0.85	0.62	NS	3.91	0.39	0.28	NS	52	Observational/ Cohort study (no intervention)	Braybrooke, J 2007
	Symptomatic hip dysplasia	Bernese periacetabular osteotomy	15.30	1.53	0.70	NS	3.70	0.37	0.17	NS		Observational/ Cohort study (no intervention)	van, Bergayk AB 2002
	Systemic sclerosis	Non-CAM	-2.60				-2.00					Randomized, comparative trial (no placebo)	Hunnicutt, SE 2008
		CAM	-8.80				0.90						
		Non-CAM vs. CAM		0.62	0.23	NS		-0.29	-0.11	NS			
	Total hip replacement for osteoarthritis	Age </= 72 yr	15.35				6.57				71	Observational/ Cohort study (no intervention)	Nilsdotter, AK 2002
		Age >72 yr	10.84				5.53						
		Age </= 72 yr vs. Age >72 yr		0.45	0.25	NS		0.10	5.82	NS			
	Vertebral and hip fractures	Vertebral fracture	-2.32				-1.49				75	Observational/ Cohort study (no intervention)	Hallberg, I 2009
		Hip fracture	-5.02				2.18						
		Vertebral fracture vs. Hip fracture		0.27	0.11	NS		-0.37	-0.15	NS			
Neurology	High grade glioma	Short-term	-0.27				-2.83				48.5	Observational/	Bosma, I

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		survivors										Cohort study (no intervention)	2009
		Long-term survivors	7.72				5.04						
		Short-term survivors vs. Long-term survivors		-0.80	-0.23	NS		-0.79	-0.22	NS			
	Lyme disease	Ceftriaxone and doxycycline	-14.20				-25.70				53.5	Randomized, placebo-controlled trial	Klempner, MS 2001
		Placebo	-20.50				-20.50						
		Ceftriaxone and doxycycline vs. Placebo		0.63	0.36	NS		-0.52	-0.30	NS			
	Migraine	Topiramide	5.70				2.20				40	Randomized, placebo-controlled trial	Dahlöf, C 2007
		Placebo	3.20				0.90						
		Topiramide vs. Placebo		0.25	0.34	NS		0.13	0.18	NS			
	Mild cognitive impairment	Exercise	2.50	0.25	0.15	NS					82	Non-randomized, comparative trial (no placebo)	Logsdon, RG 2009
		Walking	2.30				0.70					Randomized, placebo-controlled trial	van, Uffelen JG 2007
		Placebo activity	1.10				0.60						
		Vitamin	1.90				0.30						
		Placebo	1.50				1.00						
		Walking vs. Placebo activity		0.12	7.40	NS		0.01	6.16	NS			
		Walking vs. Vitamin		0.04	2.49	NS		0.04	2.49	NS			
		Walking vs. Placebo		0.08	4.91	NS		-0.03	-1.84	NS			
	Neurocognitive Dysfunction	After cardiac surgery	5.00	0.50	0.52	NS	1.00	0.10	0.10	NS	70	Observational/ Cohort study (no intervention)	Hogue, CW Jr 2008
	Stroke	Survey administration	0.80	0.08	0.25	NS	1.10	0.11	0.34	NS		Observational/ Cohort study (no intervention)	Patel, MD 2006
None	Fecal incontinence	Sacral nerve stimulation	8.48	0.85	0.52	NS	1.61	0.16	9.82	NS		Observational/ Cohort study (no intervention)	Hetzer, FH 2007
	Healthy middle age individuals	Men	-1.00				0.40					Observational/ Cohort study (no intervention)	Singh-Manoux, A 2005
		Women	-0.70				0.70						
		Men vs. Women		-0.03	-0.10	NS		-0.03	-0.10	NS			
	Healthy orthopedic surgeon residents	Healthy orthopedic surgeon residents	-4.19	-0.42	-0.16	NS	-0.79	-0.08	-3.06	NS	31	Observational/ Cohort study (no intervention)	Zahrai, A 2008
	Obesity	Diet and exercise	1.80	0.18	0.28	NS	-0.18	-0.02	-2.82	NS		Observational/ Cohort study (no intervention)	Ross, KM 2009
	Population survey	Survey-male	10.70				-2.30					Non-randomized, comparative trial (no placebo)	Morrison, DS 2004
		Survey-female	16.10				0.80						
		Survey male vs. Survey-female		-0.54	-0.28	NS		-0.31	-0.16	NS			
	Sick leave	Solution-focused	0.82				7.36				37.5	Randomized, comparative trial (no placebo)	Nystuen, P 2006
		Control	-0.20				4.39						
		Solution-focused vs. Control		0.10	5.19	NS		0.03	0.15	NS			

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None	Tobacco dependence	Smoking cessation	6.36	0.64	0.64	NS	9.72	0.97	0.97	NS		Non-randomized, comparative trial (no placebo)	Sales, MPU 2009
Nutritional	Healthy individuals	Multivitamin and mineral supplements	1.02	0.10	Inc	Inc	0.98	0.10	Inc	Inc		Randomized, placebo-controlled trial	Barringer, TA 2003
	Healthy individual	Vegan diet	1.20	0.12	0.12	NS	5.90	0.59	0.61	NS	53	Observational/ Cohort study (no intervention)	Link, LB 2008
	Obesity	Cognitive behavioral therapy	4.00				5.00				43	Non-randomized, comparative trial (no placebo)	Marchesini, G 2002
		Control	0.00				0.00						
		Cognitive behavioral therapy vs. Control		0.40	0.26	NS		0.50	0.32	NS			
	Postmenopausal women	Weight loss	2.40				0.30				58	Observational/ Cohort study (no intervention)	Yankura, DJ 2008
		Weight stable	0.71				-0.02						
		Weight regain	1.70				-2.00						
		Weight loss vs. Weight stable		0.17	0.10	NS		0.03	1.93	NS			
		Weight loss vs. Weight regain		0.07	3.80	NS		0.23	0.12	NS			
	Type 2 diabetes	Intervention	8.24				6.69				49.5	Randomized, comparative trial (no placebo)	Al Mazzrou, NR 2009
		Control	-0.54				-1.08						
		Intervention vs. Control		0.88	0.68	NS		0.78	0.60	NS			
Other	Allergies, anxiety, asthma, allergic rhinitis, depression, migraine, multiple infections, sleep disorders, headache	Adults	0.44				2.00				23.5	Observational/ Cohort study (no intervention)	Witt, CM 2008
		Children	-4.40				-4.40						
		Adults vs. Children		0.48	1.16	NS		0.64	1.53	NS			
	Any cancer	Control	0.80				0.40				47	Randomized, comparative trial (no placebo)	Adamsen, L 2009
		High intensity exercise	3.20				4.20						
		Control vs. High intensity exercise		-0.24	-0.20	NS		-0.38	-0.31	NS			
	Breast cancer	High-risk for breast cancer	-0.33	-0.03	-5.96	NS	0.94	0.09	0.17	NS	41	Observational/ Cohort study (no intervention)	Rijnsburger, AJ 2004
	Cancer patients – mainly gastrointestinal	Eprex group	5.34				8.23					Randomized, comparative trial (no placebo)	Lindholm, E 2004
		Indomethacin group	-0.70				-1.20						
		Eprex group vs. Indomethacin group		0.60	Inc	Inc		0.94	Inc	Inc			
	Cataract	Cataract surgery	-1.90				4.10				84	Observational/ Cohort study (no intervention)	Owsley, C 2007
		No cataract surgery	-0.30				4.40						
		Cataract surgery vs. No cataract surgery		-0.16	-5.06	NS		-0.03	-9.49	NS			
Other	Choroidal melanoma	Enucleation	-3.40				1.90				62.5	Observational/ Cohort study (no intervention)	Melia, M 2006
		Lodine 125 brachyotherapy	-2.90				5.10						
		Enucleation vs.		-0.05	-0.04	NS		-0.32	-0.23	NS			

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		Lodine 125 brachyotherapy											
	Choroidal neovascularization (CNV)	Submacular surgery	-4.00				1.00					Randomized, comparative trial (no placebo)	Miskala, PH 2004
		Observation	-4.00				-1.00						
		Submacular surgery vs. Observation		0.00	0.00	NS		0.20	0.21	NS			
	Chronic pain syndrome	Mindfulness-based stress reduction					7.00				46	Randomized, comparative trial (no placebo)	Plews-Ogan, M 2005
		Massage					0.00						
		Usual care					0.00						
		Mindfulness-based stress reduction vs. Massage						0.70	Inc	Inc			
		Mindfulness-based stress reduction vs. Usual care						0.70	Inc	Inc			
	Cushing's Syndrome	Group 1-Pre Rx	13.20	1.32	0.63	NS	11.70	1.17	0.56	NS	44	Multiple	Lindsay, JR 2006
	Former smoker	1 year smoking cessation	5.60	0.56	0.68	NS	4.70	0.47	0.57	NS	53	Observational/ Cohort study (no intervention)	Croghan, IT 2005
	Frail elderly living at home		-0.81	-0.08	-4.99	NS	0.70	0.07	4.32	NS	81	Observational/ Cohort study (no intervention)	Vincent, C 2006
	Gulf war veterans' illnesses	Cognitive behavioral therapy + exercise	1.03				2.30				40	Randomized, comparative trial (no placebo)	Donta, ST 2003
		Exercise	0.97				2.33						
		Cognitive behavioral therapy	0.57				0.97						
		Usual care	-0.04				-1.03						
		Cognitive behavioral therapy + exercise vs. Exercise		0.01	6.94	NS		0.00	-3.47	NS			
		Cognitive behavioral therapy + exercise vs. Cognitive behavioral therapy		0.05	5.40	NS		0.13	0.16	NS			
		Cognitive behavioral therapy + exercise vs. Usual care		0.11	0.12	NS		0.33	0.39	NS			
	Head and neck cancer	Intervention	-3.44	-0.34	-0.61	NS	3.18	0.32	0.56	NS	59	Observational/ Cohort study (no intervention)	Ronis, DL 2008
	Healthy African Americans	Survey administration	-0.63	-0.06	Inc	Inc	0.41	0.04	Inc	Inc	57	Observational/ Cohort study (no intervention)	Wolinsky, FD 2009
Other	Healthy elderly	Exercise program	2.95	0.30	1.41	NS	2.65	0.27	1.27	NS	75	Randomized,	Munro, JF

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												comparative trial (no placebo)	2004
	Healthy individuals	SF-36 telephone first adm.	-0.80				-0.70					Randomized, comparative trial (no placebo)	Garcia, M 2005
		SF-36 self first adm.	1.00				2.20						
		SF-36 telephone first adm. vs. SF-36 self first adm.		-0.18	-0.15	NS		-0.29	-0.23	NS			
		Men	-3.20				1.10					Observational/ Cohort study (no intervention)	Stafford, M 2008
		Women	-3.70				1.20						
		Men vs. Women		0.05	0.21	NS		-0.01	-0.04	NS			
	Hepatitis C	Pegylated interferon alpha-2b	-3.54				-3.48					Non-randomized, comparative trial (no placebo)	Mathew, A 2006
		Control	-2.83				-3.79						
		Pegylated interferon alpha-2b vs. Control		-0.07	-3.25	NS		0.03	1.42	NS			
	HIV	Low chaos	-0.50				0.90					Observational/ Cohort study (no intervention)	Wong, MD 2007
		High chaos	0.00				3.10						
		Low chaos vs. High chaos		-0.05	Inc	Inc		-0.22	Inc	Inc			
	Multiple chronic conditions	Eurythmy therapy	3.97	0.40	0.81	NS	6.70	0.67	1.37	NS	56	Observational/ Cohort study (no intervention)	Hamre, HJ 2007
	Obstructive sleep apnea	CM, conservative measures	-1.15				2.15				45.67	Randomized, comparative trial (no placebo)	Lam, B 2007
		CPAP, continuous positive airway pressure	3.15				4.37						
		OA, oral appliance	-0.12				4.52						
		CM, conservative measures vs.		-0.43	-0.18	NS		-0.22	-9.07	NS			
		CM, conservative measures vs.		-0.10	-4.21	NS		-0.24	-9.69	NS			
	Pan-hypopituitarism	Female-placebo	1.54				1.05				47.25	Randomized, placebo-controlled trial	Brooke, AM 2006
		Female-DHEA	3.74				1.52						
		Male-placebo	-0.96				-0.77						
		Male-DHEA	0.99				-0.75						
		Female-placebo vs. Female-DHEA		-0.22	-6.01	NS		-0.05	-1.26	NS			
		Female-placebo vs. Male-placebo		0.25	6.55	NS		0.18	4.78	NS			
		Female-placebo vs. Male-DHEA		0.05	1.31	NS		0.18	4.34	NS			
	Severe sepsis	6 months follow-up after sepsis treatment	-2.70	-0.27	Inc	Inc	2.40	0.24	Inc	Inc	69	Observational/ Cohort study (no intervention)	Hofhuis, JG 2008
Other	Type 2 diabetes	Intensive treatment	-0.09				2.81				60	Randomized, comparative trial (no placebo)	Janssen, PG 2009
		Routine treatment	-1.40				4.62						
		Intensive treatment vs. Routine treatment		0.13	0.15	NS		-0.18	-0.20	NS			

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Psychiatric Disorders	Alcohol dependence	Standard care	11.20				17.00				47.5	Randomized, placebo-controlled trial	Kiritzé-Topor, P 2004
		Plus acamprosate	16.90				24.50						
		Standard care vs. Plus acamprosate		-0.57	-0.59	NS		-0.75	-0.77	NS			
	Alcohol dependency	XR-NTX	0.20				8.20				45	Randomized, placebo-controlled trial	Pettinati, HM 2009
		Placebo	-0.10				6.20						
		XR-NTX vs. Placebo		0.03	3.05	NS		0.20	0.20	NS			
	Bipolar disorder	BCM	-0.80				1.70				55	Randomized, comparative trial (no placebo)	Kilbourne, AM 2008
		Usual care	-0.90				-0.90						
		BCM vs. Usual care		0.01	3.80	NS		0.26	9.88	NS			
	Depression	Intervention	-2.90				9.40				78	Randomized, comparative trial (no placebo)	Cole, MG 2006
		Usual care	-2.70				9.20						
		Intervention vs. Usual care		-0.02	-1.25	NS		0.02	1.25	NS			
		Paroxetine	-3.11				-15.10				46	Randomized, comparative trial (no placebo)	Kroenke, K 2001
		Fluoxetine	-0.99				-15.90						
		Sertraline	-2.67				-13.50						
		Paroxetine vs. Fluoxetine		-0.21	-0.21	NS		0.08	7.82	NS			
		Paroxetine vs. Sertraline		-0.04	-0.04	NS		-0.16	-0.16	NS			
	Depression after CABG	Telephone delivered collaborative care	12.80				6.90				64	Randomized, comparative trial (no placebo)	Rollman, BL 2009
		Control	11.10				3.70						
		Telephone delivered collaborative care vs. Control		0.17	0.15	NS		0.32	0.28	NS			
	Depression and alcoholism	Sertraline	2.00				8.00				46.5	Randomized, placebo-controlled trial	Gual, A 2003
		Placebo	4.00				4.00						
		Sertraline vs. Placebo		-0.20	-9.09	NS		0.40	0.18	NS			
	Depression/ Anxiety	Control	-0.24				0.60				68	Randomized, comparative trial (no placebo)	Antunes, HK 2005
		Endurance exercise program	3.77				7.55						
		Control vs. Endurance exercise program		-0.40	-0.14	NS		-0.70	-0.24	NS			
	Emotional stress in people with chronic illnesses	Intervention group	2.13				12.19				43	Non-randomized, comparative trial (no placebo)	Roth, B 2004
		Comparison group	-4.75				5.44						
		Intervention group vs. Comparison group		0.69	0.26	NS		0.68	0.25	NS			
	HRQoL in depressed patients on medications and non-depressed patients undergoing gastric bypass surgery	Antidepressant	16.22				2.85				41	Non-randomized, comparative trial (no placebo)	Love, RJ 2008
		Non-antidepressant	12.10				4.58						
		Antidepressant vs. Non-antidepressant		0.41	0.22	NS		-0.17	-9.19	NS			
	Major psychiatric	Integrated care	4.70				2.40				45.5	Randomized,	Druss, BG

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	disorders	Usual care	-0.30				2.00					comparative trial (no placebo)	2001
		Integrated care vs. Usual care		0.50	0.27	NS		0.04	2.19	NS			
	Mental health	Intervention	0.28				1.80				54.5	Randomized, placebo-controlled trial	Reijneveld, SA 2003
		Control	-0.20				-2.27						
		Intervention vs. Control		0.05	2.27	NS		0.41	0.19	NS			
	Social anxiety disorder	Control	1.33				-4.62				40.5	Randomized, placebo-controlled trial	Franēois, C 2008
		Escitalopram	-0.29				0.04						
		Control vs. Escitalopram		0.16	0.15	NS		-0.47	-0.44	NS			
	Treatment-resistant depression	Cognitive behavioral therapy	4.38	0.44	0.29	NS	15.33	1.53	1.01	NS	41	Non-randomized, comparative	Matsunaga, M 2010
Pulmonary	COPD	BTS guidelines	-0.50				-4.45					Observational/ Cohort study (no intervention)	Guest, JF 2005
		Control	-3.82				-2.59						
		BTS guidelines vs. Control		0.33	0.37	NS		-0.19	-0.21	NS			
Renal	End stage renal disease	Hemodialysis	0.60				1.60				56	Observational/ Cohort study (no intervention)	Wu, AW 2004
		Peritoneal dialysis	-0.70				1.70						
		Hemodialysis vs. Peritoneal dialysis		0.13	0.17	NS		-0.01	-0.01	NS			
	On hemodialysis	Medication	8.16				5.84				43.5	Randomized, placebo-controlled trial	Rathod, R 2006
		Placebo	-0.44				-7.42						
		Medication vs. Placebo		0.86	0.19	NS		1.33	0.30	NS			
	Renal failure	Renal transplanted patients	3.90	0.39	0.22	NS	-2.80	-0,28	-0.16	NS	51	Observational/ Cohort study (no intervention)	Rebollo, P 2003
	Small renal cell carcinoma	RFA	3.47				6.00				59.5	Non-randomized, comparative trial (no placebo)	Onishi, T 2007
		Lap	-4.16				4.47						
		RFA vs. Lap		0.76	0.23	NS		0.15	4.61	NS			
	Urology	Intervention	-0.85	-0.09	-9.04	NS	2.62	0.26	0.28	NS		Observational/ Cohort study (no intervention)	Namiki, S 2005
Respiratory Disorders	Acute COPD exacerbation	Usual care	6.00				5.60				70.5	Randomized, comparative trial (no placebo)	Man, WD 2004
		Early rehab	16.70				25.70						
		Usual care vs. Early rehab		-1.07	-0.31	NS		-2.01	-0.58	NS			
	Acute respiratory distress syndrome (ARDS)	ARDS survivors	5.14	0.51	Inc	Inc	10.21	1.02	Inc	Inc	45	Observational/ Cohort study (no intervention)	Herridge, MS 2003
	Chest pain	CPU	2.06				0.10				49.5	Randomized, comparative trial (no placebo)	Goodacre, S 2004
		Routine	0.82				-0.55						
		CPU vs. Routine		0.12	Inc	Inc		0.07	Inc	Inc			
	Chronic lung diseases	COPD	4.00				3.00				59	Observational/ Cohort study (no intervention)	Windisch, W 2008
		Restrictive lung disease	7.00				5.00						
		Neuromuscular disease	-4.00				7.00						
		Obesity hypoventilation syndrome	8.00				9.00						

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		COPD vs. Restrictive lung disease		-0.30	-0.11	NS		-0.20	-7.62	NS			
		COPD vs. Neuromuscular disease		0.80	0.26	NS		-0.40	-0.13	NS			
		COPD vs. Obesity hypoventilation syndrome		-0.40	-0.10	NS		-0.60	-0.16	NS			
	Chronic sinusitis	Homeopathic treatment	4.92	0.49	0.57	NS	9.84	0.98	1.14	NS	40	Observational/ Cohort study (no intervention)	Witt, CM 2009
	COPD	Pulmonary rehabilitation	1.43	0.14	8.67	NS	4.72	0.47	0.29	NS	66	Non-randomized, comparative trial (no placebo)	Boueri, FM 2001
		Air group	1.12				-0.45				65.5	Randomized, comparative trial (no placebo)	Eves, ND 2009
		Helium hyperoxia group	0.76				5.75						
		Air group vs. Helium hyperoxia group		0.04	0.01	NS		-0.62	-0.19	NS			
		Rehabilitation group	25.70				12.70				56.5	Non-randomized, comparative trial (no placebo)	Ghanem, M 2010
		Control group	6.60				2.00						
		Rehabilitation group vs. Control group		1.91	0.57	NS		1.07	0.32	NS			
Respiratory Disorders		Usual care	-3.03				-0.65				68.67	Randomized, comparative trial (no placebo)	Coultas, D 2005
		Nurse-assisted medical management	-0.89				-2.16						
		Nurse-assisted collaborative management	0.20				-1.92						
		Usual care vs. Nurse-assisted medical management		-0.21	-0.13	NS		0.15	9.11	NS			
		Usual care vs. Nurse-assisted collaborative management		-0.32	-0.19	NS		0.13	7.63	NS			
		Pulmonary rehabilitation	-0.38	-0.04	Inc	Inc	1.92	0.19	Inc	Inc	63	Non-randomized, comparative trial (no placebo)	de Torres, JP 2002
		Cylinder oxygen	1.78	0.18	Inc	Inc	4.16	0.42	Inc	Inc	67	Randomized, placebo-controlled cross-over trial	Eaton, T 2002
	Emphysema	Pulmonary rehabilitation	1.30	0.13	0.45	NS	2.20	0.22	0.77	NS	67	Observational/ Cohort study (no intervention)	Ries, AL 2005
		Intervention	5.00	0.50	0.71	NS					61	Observational/ Cohort study (no	Yusen, RD 2003

Therapeutic Area	Condition	Treatments	PCS Change Difference	PCS Change Effect Size	PCS Change T[1]	PCS Change Sign[2]	MCS Change Difference	MCS Change Effect Size	MCS Change T[1]	MCS Change Sign[2]	Average Age	Study Design	Citation
												intervention)	
	Restrictive lung disease and COPD	Restrictive lung disease	2.24				7.09				68.5	Non-randomized, comparative trial (no placebo)	Kagaya, H 2009
		COPD	0.93				6.18						
		Restrictive lung disease vs. COPD		0.13	5.20	NS		0.09	3.61	NS			
	Severe acute respiratory syndrome (SARS)	Control	0.62				2.43				37	Randomized, comparative trial (no placebo)	Lau, HM 2005
		Exercise	2.06				0.62						
		Control vs. Exercise		-0.14	-8.28	NS		0.18	0.10	NS			
	SARS	SARS Survivors	-12.00	-1.20	-1.30	NS	7.00	0.70	0.76	NS	42	Observational/ Cohort study (no intervention)	Tansey, CM 2007
	Sleep apnea	Continuous positive airway pressure	1.47	0.15	0.14	NS	7.85	0.79	0.74	NS		Observational/ Cohort study (no intervention)	Flemons, WW 2002
		Real	8.80				14.60				48.5	Randomized, placebo-controlled trial	Siccoli, MM 2008
		Sham	0.60				3.80						
		Real vs. Sham		0.82	0.41	NS		1.08	0.55	NS			
Respiratory Disorders		Autotitration	16.30				22.10				45.67	Randomized, comparative trial (no placebo)	West, SD 2006
		Mixed autotitration and fixed pressure	19.50				24.70						
		Control	20.70				26.10						
		Autotitration vs. Mixed autotitration and fixed pressure		-0.32	-0.13	NS		-0.26	-0.10	NS			
		Autotitration vs. Control		-0.44	-0.18	NS		-0.40	-0.16	NS			
	Sleep apnea and nasal obstruction	Intervention	0.42	0.04	3.01	NS	6.07	0.61	0.43	NS	39	Observational/ Cohort study (no intervention)	Li, HY 2008
Surgical	Breast cancer biopsy	Vacuum-assisted breast biopsy	-4.00	-0.40	-0.40	NS	1.80	0.18	0.18	NS	51	Observation/ Cohort study (no intervention)	Domeyer, PJ 2010
	Coronary artery disease	Patient with CABG	12.20	1.22	1.34	NS	22.01	2.20	2.41	S	70	Observational/ Cohort study (no intervention)	Aydin, S 2006
	End stage liver disease	Liver transplant	-31.19	-3.12	Inc	Inc	-38.32	-3.83	Inc	Inc		Observational/ Cohort study (no intervention)	Ratcliffe, J 2002
	Epiretinal membranes	Virectomy and epiretinal membrane peel surgery	0.06	0.01	2.63	NS	-1.53	-0.15	-6.84	NS		Observational/ Cohort study (no intervention)	Ghazi-Nouri, SM 2006
	Fibromyalgia with cervical myelopathy	Surgery	10.70				8.60					Observational/ Cohort study (no intervention)	Heffez, DS 2007
		Control	3.30				0.00						
		Surgery vs. Control		0.74	0.31	NS		0.86	0.36	NS			
	Gastric bypass surgery	Gastric bypass surgery	17.82	1.78	Inc	Inc	8.22	0.82	Inc	Inc	44	Observational/ Cohort study (no intervention)	Tompkins, J 2008
	Inguinal hernia	Surgical repair	0.13								57	Randomized, comparative trial (no placebo)	Fitzgibbons, RJ Jr 2006
		Watchful waiting	0.29										
		Surgical repair vs.		-0.02	-0.02	NS							

Therapeutic Area	Condition	Treatments	PCS Change Difference	PCS Change Effect Size	PCS Change T[1]	PCS Change Sign[2]	MCS Change Difference	MCS Change Effect Size	MCS Change T[1]	MCS Change Sign[2]	Average Age	Study Design	Citation
		Watchful waiting											
	Lumbar spinal stenosis	Bilateral decompression	8.44	0.84	Inc	Inc	2.23	0.22	Inc	Inc	70	Observational/ Cohort study (no intervention)	Cavuşoğlu, H 2007
	Metastatic breast cancer	Intervention	2.25	0.22	0.14	NS	6.35	0.63	0.40	NS		Observational/ Cohort study (no intervention)	Amado, F 2006
	Obstructive sleep apnea	Extended uvuloplatal flap surgery	0.26	0.03	1.90	NS	11.24	1.12	0.83	NS	45	Observational/ Cohort study (no intervention)	Li, HY 2004
Surgical	Oropharyngeal cancer	Chemoradiation	-2.69				3.99				56.5	Non-randomized, comparative trial (no placebo)	Donatelli-Lassig, AA 2008
		Chemoradiation with neck dissection	-3.92				5.52						
		Chemoradiation vs. Chemoradiation with neck dissection		0.12	6.04	NS		-0.15	-7.50	NS			
	Osteoarthritis	Total hip arthroplasty	13.63				3.81					Non-randomized, comparative trial (no placebo)	Kiebzak, GM 2002
		Total knee arthroplasty	7.57				1.08						
		Total hip arthroplasty vs. Total knee arthroplasty		0.61	0.71	NS		0.27	0.32	NS			
	Pain	Pain patients	6.40	0.64	0.39	NS	1.90	0.19	0.12	NS	68	Observational/ Cohort study (no intervention)	Wu, CL 2003

[1]Standard T statistic.

[2]S is defined as significant at the α=0.05 level when the T statistic is ≥ 1.96 or ≤ -1.96. NS is non-significant at the α=0.05 level.

[*]"Inc" refers to incomplete information supplied by the study (eg. sample size(s) by group(s) or arm(s) of study). Unable to calculate a T statistic and associated P value for significance.

	Total knee arthroplasties	Intervention	8.70	0.87	1.45	NS	2.40	0.24	0.40	NS	69	Observational/ Cohort study (no intervention)	Jones, CA 2003

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Table 5: Summary of Treatment Effects by Effect Size Categories

	Small Effect Size: (0.2 to 0.4)		Moderate Effect Size (0.5 to 0.7)		Large Effect Size (0.8 or greater)	
	Condition	Change in health	Condition health effects	Change in health	Condition health effects	Change in health
Change in PCS	back pain/sciatica	Progressive resistance exercise in elderly patients with diabetes (Tamari et al., 2009)	Limitations in use of arm/leg	Ablation of atrial fibrillation (Berkowitsch et al., 2003)	Impact of severe congestive heart failure	Coronary arterial bypass grafting (Aydin et al. 2006)
	Angina	Cardiac rehabilitation post MI (Izawa et al., 2004)	Congestive heart failure	Surgery vs. medication in multivessel coronary disease (Krecki et al., 2010)	Impact of rheumatoid arthritis	Total hip replacement (Beaupre, LA 2001) Total knee replacement (Baumann, C 2009)
	Type II diabetes	Peripheral endovascular revascularization (Safley et al., 2007)	Osteoarthritis	Esomeprazole for GERD (Kulig et al., 2003)		Lumbar spine surgery (Braybrooke et al. 2007)
	Past Myocardial infarction	Surgery for prostate cancer vs. Radiation therapy (Hu et al., 2006)	Duodenal ulcer	Adalimumab vs. placebo for ankylosing spondylitis (Davis jr. et al., 2007)		Sacral nerve stimulation for fecal incontinence (Hetzer, et al. 2007)
	Impact of chronic lung disease	Hydrotherapy vs. control for osteoarthritis (Fransen et al., 2007)		1 year after smoking cessation (Croghan et al., 2005)		Gastric bypass surgery (Tompkins et al. 2008)
	Irritable Bowel Disease	Cognitive behavioral therapy vs. control for obese patients (Marchesini et al., 2002)		Integral care vs. usual care for major psychiatric disorders (Druss et al., 2001)		Individualized exercise program and long-term telephone follow-up to prevent early readmissions (Courtney et al., 2009)

Table 5: Summary of Treatment Effects by Effect Size Categories (continued)

	Small Effect Size: (0.2 to 0.4)		Moderate Effect Size (0.5 to 0.7)		Large Effect Size (0.8 or greater)	
	Condition	Change in health	Condition health effects	Change in health	Condition health effects	Change in health
Change in MCS	Chronic lung disease	Cardiac rehabilitation post myocardial infarction (Izawa et al., 2004)	Asthma	Progressive resistance exercise in elderly patients with diabetes (Tamari et al., 2009)	Impact of depression	Health education by a nurse in patients with CAD (McHugh et al. 2001)
	Vision impairment	Surgery for prostate cancer vs. radiation therapy (Hu et al., 2006)		Total hip replacement (Beaupre et al., 2001)		Ablation of atrial fibrillation (Berkowitsch et al., 2003)
		New antipsychotics in schizophrenia (Fleischhacker et al., 2005)		Lumbar spine surgery (Braybrooke et al., 2007)		Escitalopram in patients with hepatitis C (Gleason et al., 2005)
		Methotrexate vs. Leflunomide for rheumatoid arthritis (Davis et al., 2007)		1 year after smoking cessation (Croghan et al., 2005)		Continuous Positive Airway Pressure for sleep apnea (Flemons et al. 2002)
		Telephone delivered collaborative care vs. control (Rollman et al., 2009)		Mindfulness-based stress reduction vs. usual care for chronic pain syndrome (Plews-Ogan et al., 2005)		Coronary arterial bypass grafting (Aydin et al., 2006)
				Escitalopram for depression and alcoholism (Kroenke et al., 2001)		Gastric bypass surgery (Tompkins et al., 2008)

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