



## A randomized comparative effectiveness study of Healthy Directions 2—A multiple risk behavior intervention for primary care<sup>☆</sup>



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### ABSTRACT

**Objective.** To evaluate the effectiveness of the Healthy Directions 2 (HD2) intervention in the primary care setting.

**Methods.** HD2 was a cluster randomized trial (conducted 3/09–11/11). The primary sampling unit was provider ( $n = 33$ ), with secondary sampling of patients within provider ( $n = 2440$ ). Study arms included: 1) usual care (UC); 2) HD2—a patient self-guided intervention targeting 5 risk behaviors; and 3) HD2 plus 2 brief telephone coaching calls (HD2 + CC). The outcome measure was the proportion of participants with a lower multiple risk behavior (MRB) score by follow-up.

**Results.** At baseline, only 4% of the participants met all behavioral recommendations. Both HD2 and HD2 + CC led to improvements in MRB score, relative to UC, with no differences between the two HD2 conditions. Twenty-eight percent of the UC participants had improved MRB scores at 6 months, vs. 39% and 43% in HD2 and HD2 + CC, respectively ( $ps \leq .001$ ); results were similar at 18 months ( $p \leq .05$ ). The incremental cost of one risk factor reduction in MRB score was \$310 for HD2 and \$450 for HD2 + CC.

**Conclusions.** Self-guided and coached intervention conditions had equivalent levels of effect in reducing multiple chronic disease risk factors, were relatively low cost, and thus are potentially useful for routine implementation in similar health settings.

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### Introduction

A large percentage of health care costs are a function of the coexistence of multiple chronic diseases (Tinetti et al., 2012). One in four US adults have multimorbidities, which accounts for 60% of US health care spending. The number of Americans living with multimorbidities is increasing at a faster rate than expected (Anderson, 2010). The vast majority of older adults (73%) have multiple chronic conditions, as do a significant and growing number of people under 65 years of age (Anderson, 2010; Tinetti et al., 2012; Weiss et al., 2007).

The increasing prevalence of multimorbidities is at least in part a function of the health behavior profile of US adults, most of whom

have multiple risk factors for chronic disease. Seventy-seven percent of US adults do not meet the dietary guidelines, 49% do not meet recommended physical activity levels, and 18% are current smokers (CDC, 2012). Poor health behaviors tend to co-occur (Blair et al., 1985; Emmons et al., 1994; Gillman et al., 2001; Jeffery et al., 1993; Pirie et al., 1992; Simons-Morton et al., 1991; Troost et al., 2012; Unger, 1996), and prevalence has not changed much in the past two decades. One reason for this may be that it is inefficient to target the behavioral risk factors for multimorbidities as separate entities, especially when similar behavior change principles apply and behaviors are interrelated.

Only a few randomized control trials have intervened on multiple risk behaviors (MRBs) simultaneously (Elmer et al., 2006; Emmons et al., 2005a; Marcus et al., 1999; Resnicow et al., 2005; Spring et al., 2010, 2012b), with very limited emphasis either on multiple risk outcomes or on population level effects. These have largely been efficacy studies that include more extensive interventions than are possible in most primary care settings (Emmons et al., 2005b). To facilitate translation to practice, it is important to develop effective interventions that

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are both low in cost and have high reach. Development of sustainable interventions for primary care is particularly important given the current focus within health care reform on prevention. It is critical that we study these interventions in real-world primary care settings, and learn how to package them so that they can be sustained by health care systems.

This paper reports on the results of the Healthy Directions 2 (HD2) trial, a cluster randomized control trial used to evaluate the comparative effectiveness of two versions of a MRB intervention conducted in the primary care setting. The intervention targeted physical activity, fruit and vegetable intake, red meat consumption, multi-vitamin use, and smoking cessation. These risk behaviors are associated with the leading causes of chronic disease morbidity and mortality (Hung et al., 2004; Pan et al., 2012; U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2010; Warburton et al., 2006, 2008) and reflect behaviors that were a priority in the participating health care system. This study compares the impact of self-guided vs. coached interventions on reduction of these risk factors simultaneously. The primary comparison evaluated the outcomes of usual care (UC) compared with: (1) the self-guided Healthy Directions 2 (HD2) intervention, delivered via web or print (modality selected by the patient); and (2) the HD2 intervention plus two brief coaching calls designed to activate the use of the intervention materials (HD2 + CC). Cost-effectiveness of the interventions was a secondary outcome.

## Methods

### Study design

HD2 was a cluster randomized control comparative effectiveness trial conducted in internal medicine practices of two urban health centers of a health care delivery system in metropolitan Boston (Greaney et al., 2014). Randomization to three study arms occurred at the level of primary care provider ( $n = 33$ ): 1) UC; 2) HD2 or 3) HD2 + CC (see CONSORT diagram, Fig. 1). HD2 and HD2 + CC addressed the 5 target behaviors simultaneously. This study was conducted between March, 2009 and November, 2011. The study was approved by the Institutional Review Board at Harvard Pilgrim Health Care.

The primary sampling unit was the primary care physician (PCP) and there were 3 randomization arms. Sample size was determined using methods for studies with randomization by cluster (Donner et al., 1981), based on results from our previous trial. We estimated that the within PCP standard deviation would be .91, and the within subject correlation would be .5, yielding an estimated variance of the difference of 1.66. We have demonstrated very low values of within-center correlation, and thus estimated the within-PCP correlation ( $r$ ) to be .01. With a final projected  $N$  of 60 subjects per PCP and 11 PCPs in the usual care condition, and 90 subjects per PCP and 11 PCPs in the two intervention conditions, there was 80% power to detect a significant difference in the mean change in number of risk factors (2-sided) between any two of the conditions of 0.28 at the 5% significance level. The random allocation sequence was generated and overseen by the study biostatistician.

### Participants

Patients were eligible if they: 1) were 18+ years of age; 2) could read English; 3) had not received a diagnosis of dementia, blindness, neurodegenerative or psychiatric illness (previous 5 years); and 4) were not undergoing cancer treatment (previous 12 months). Potentially eligible patients were identified via the electronic medical record (EMR). We sent those who had a scheduled well-care visit or chronic disease management appointment an introductory letter with "opt out" information. Upon check-in, the clinic staff introduced the patient to the study staff, who confirmed eligibility and obtained informed consent. The study was presented as an effort to learn how best to help health care providers support patients to live a healthy lifestyle. Participants then completed the baseline survey. About half (52%,  $n = 2440$ ) of the patients who were approached enrolled in the study and received a \$5 gift card after the baseline survey. We collected follow-up data via a telephone survey at the end of the 6-month intervention and at 18 months; completers received \$5 and \$20 gift cards, respectively. The data collection team was blind to condition assignment. The retention rates were 68% at 6 months and 71% at 18-months. We received IRB approval to pull de-identified aggregate data on non-enrollees.

### Intervention conditions

#### Usual care (UC)

UC participants received the current standard of care offered by their individual provider; the participating practices did not have a standard practice protocol for the target behaviors, with the exception of a referral service for the state tobacco control program. Thus, provision of standard materials ensured that all UC participants received at least basic messages about the target risk factors. Four basic health promotion brochures, published by the American Cancer Society, were provided to the UC condition participants: Living Smart; Choices for Good Health; Cooking Smart; and Take Control of Your Health. A smoking cessation brochure, from the state of Massachusetts' Tobacco Control Program, was also provided.

#### HD2 intervention (HD2)

The intervention focused on influences at the individual, interpersonal, and community levels (McLeroy et al., 1988; Sorensen et al., 2003) that could motivate and maintain behavior change and be sustainable. Components included: 1) provider endorsement using a brief script (<30 s); 2) intervention materials via web or print (patient choice) which included national recommendations in the 5 behavioral areas: quit smoking if a smoker, eat  $\leq 3$  servings of red meat per week, eat 5–9 servings of fruits and vegetables daily, get at least 30 min of moderate physical activity 5 or more days per week and/or walk at least 10,000 steps per day, and take a daily multi-vitamin; tracking of each health behavior was available on a daily basis; tips and resources to meet the recommendations were provided; 3) two tailored feedback reports (post-baseline and 6-months) focused on behaviors for which participants were/were not meeting guidelines; 4) materials for participants' social network to support their behavior change efforts; and 5) links to key community-based resources. Participants in the HD2 arms received a bottle of multivitamins and a pedometer.

The materials emphasized changing multiple behaviors simultaneously and focused on behavioral tracking and action planning. The website had planning and tracking components for daily reporting on the target behaviors and provided feedback on progress over time. The print materials had a similar mechanism designed for a paper format. Action planning was introduced in the "Welcome" booklet, where participants were encouraged to use the "Plan My Changes" booklet to formulate reasonable and specific health goals and think about how to reach them. Barrier reduction tips were provided. Participants chose the behaviors they wished to change and were able to document specific ways in which to achieve the goal(s). Participants were given two "Plan My Changes" booklets, one to be used at the beginning of the intervention and one to be used 3 months later. Print participants were also given a "Track My Changes" booklet, which included printed log sheet that let them track their progress on a daily and weekly basis.

#### HD2 intervention plus coaching (HD2 + CC)

Participants in this arm received all of the HD2 components plus two brief coaching calls, at 2 and 6 weeks after enrollment. The health coaches were trained in the principles of brief motivational interviewing (Miller and Rollnick, 1991). The calls were 5–10 min and focused on increasing engagement with the intervention, selecting achievable goals, and developing strategies to address barriers and meet selected goals.

### Primary outcome measure

The primary outcome measure was the multiple risk behavior (MRB) score, which ranged from 0 (met all behavioral recommendations) to 5 (met none of the recommendations). One point was given for each behavioral risk factor not met. Participants reported on all targeted behaviors and the results for each behavior were dichotomized as to whether a person did or did not meet recommended guidelines. Participants with incomplete data for one or more behaviors at baseline assessment were classified as not meeting those behavioral recommendations ( $n = 61$ ). Physical activity was assessed using the CDC's Behavioral Risk Factor Surveillance Survey (BRFSS) measure that evaluates moderate activity (brisk walking, biking or anything that causes small increases in breathing or heart rate) and vigorous activity (running, aerobics or anything else that causes large increases in breathing or heart rate) during a usual week (Estabrooks et al., 2008; Macera et al., 2001). Reported minutes of moderate and vigorous physical activity were summed into a total number of weekly minutes, and then dichotomized as to whether a person met the current recommendation of 150+ min of moderate activity or 60+ min of vigorous activity or the equivalent per week (U.S. Department of Health and Human Services, 2008).

Fruit and vegetable intake was assessed using the "5 A Day for Better Health" tool, a validated 7-item instrument covering different types of fruit and

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