Title of Project: A Randomized Trial of Home Self-Efficacy Enhancement

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Abstract

Purpose: To determine whether Homing in on Health (HIOH), a variant of the peer-led Chronic Disease Self-Management Program (CDSMP), improves patient outcomes at 1 year.

Scope: The group-format CDSMP improves some outcomes at 4-6 months. It is unclear whether 1-to-1 delivery of the program is effective or whether certain variables moderate its effects.

Methods: In total, 415 outpatients aged $\geq$ 40 with various chronic conditions were enrolled in an RCT of HIOH, delivered over 6 weeks in participants' homes or via telephone, versus usual care. *Outcomes*: SF-36 Physical and Mental Component Summary scores (primary), illness management self-efficacy, EuroQol Visual Analog Scale (EQ VAS), depressive symptoms, and health expenditures. Personality and perceived self-management control were measured at baseline.

Results: In-home (but not telephone) HIOH led to significantly higher self-efficacy at 6 weeks (effect size = 0.27, 95% CI = 0.10, 0.43), an effect attenuated by 1 year. Of other 1-year outcomes, only EQ VAS scores were significantly improved (effect size = 0.40, 95% CI = 0.14, 0.66). HIOH enhanced self-efficacy primarily in participants with (a) more depressive symptoms; (b) lower perceived control; and (c) higher levels of Neuroticism and/or lower levels of Conscientiousness, Agreeableness, and Extraversion. Additional studies are required to explore long-term effects of the CDSMP.

Keywords: chronic disease; Chronic Disease Self-Management Program; depression; effect modifiers; health status; internal-external control; personality; randomized controlled trials; self care; self-efficacy

Purpose

Peer-led interventions to help patients manage health conditions hold promise as a cost-effective approach to improving long-term chronic illness outcomes. Perhaps the best known and studied of such interventions is the Stanford Chronic Disease Self-Management Program (CDSMP). Yet despite its literally global dissemination and supporting research evidence, a number of key questions regarding the program remain, including the duration and moderators of its effects. The research summarized in this final report begins to fill these important research gaps.

Objectives of Study. We conducted a 1-year RCT of Homing in on Health (HIOH), a 1-to-1, home-delivered variant of the CDSMP. The original CDSMP is provided to small groups in centralized community locations. We aimed to make its content available to those less able to participate due to functional limitations, transportation problems, and/or discomfort with groups. The study goals were to determine whether in-home and/or telephone HIOH would enhance illness management self-efficacy and improve outcomes for persons with chronic conditions. We explored telephone delivery, because it has been used to provide other successful peer interventions at relatively little effort.(1-3) Specific study hypotheses were:

(1). Compared with controls, HIOH participants will have significantly better illness management self-efficacy and self-rated physical and mental health and significantly fewer hospitalizations and total healthcare expenditures at 1 year, with no significant differences between the in-home and phone intervention groups.

(2). The self-efficacy-enhancing effects of HIOH will be greatest in those with (a) higher levels of Neuroticism and/or lower levels of Extraversion, Openness, Agreeableness, and/or Conscientiousness (Five-Factor Model personality factors); (b) more depressive symptoms; and/or (c) lower perceived control over illness self-management.

Scope

Background. Research provides support for the effectiveness of the CDSMP, which aims to enhance illness management self-efficacy, or confidence to execute daily behaviors required to manage chronic conditions, regardless of specific diagnosis.(4) In randomized controlled trials (RCTs), the original CDSMP (5, 6) and several variants (7-11) improved self-efficacy, improved certain subfacets of self-rated health, and, in some studies, reduced healthcare utilization. (6, 7, 9)

Context. Nonetheless, a number of questions remain regarding the program. First, not all RCTs of the CDSMP have had positive findings. (12, 13) Second, all but one prior study employed relatively short, 4- to 6-month follow-up intervals. The only 1-year RCT, which involved an internet variant, found a small effect on health distress and no effects on self-rated health or utilization. (10) Thus, it is unclear whether the program improves outcomes beyond 6 months. Third, it is also unclear whether 1-to-1 delivery of the program would be effective. Fourth, potential *moderators* of the program's effects – variables that specify for whom or under what conditions it works – have not previously been explored. At a theoretical level, identifying treatment moderators may lead to increased understanding about for whom the intervention works. (14) At a practical level, understanding moderators can help healthcare providers and administrators increase intervention delivery efficiency, or the ratio of clinical benefit to delivery effort (15), by identifying those for whom the intervention is most likely to be effective.

Although a number of patient dispositional characteristics might be expected to moderate the effects of the intervention, several appear particularly ripe for exploration in this regard, both in terms of their feasibility of measurement and potential for clinical targeting. The first grouping are Five-Factor Model (FFM) personality factors (16, 17): Neuroticism, Extraversion, Openness, Agreeableness, and Conscientiousness. Prior studies exploring the degree of correlation between FFM factors and the construct of general self-efficacy have been intriguing (18, 19) but also had limited applicability to the question of whether FFM factors moderate the self-efficacy enhancing effects of disease self-management interventions.

A second putative psychological moderator of the effects of the CDSMP, again based on prior suggestive research concerning its reciprocal relationship with self-efficacy(1, 3, 20-30), is depressive symptoms. However, given ambiguities in the prior literature, studies simultaneously examining the effect of self-efficacy enhancing interventions in depressed versus non-depressed patients and exploring reciprocal relationships between these constructs were needed.

A third putative moderator is perceived control over self-management behaviors. Bandura suggests that, even when all the "tools" for achieving a given health behavior are objectively present, people who perceive little control over the behavior may display lower self-efficacy for attaining the behavior than do those who perceive it to be largely within their control. (31) Qualitative data from focus groups we conducted with chronically ill patients prior to our RCT (see #5 under "List of Publications and Products") also provided some support for this assertion.(32) However, no RCTs had explored the potential moderating effect of perceived control on the CDSMP.

Setting. Study activities were conducted from July 2003 to June 2008. The local Institutional Review Board approved the various study protocols. Participants for this study were recruited from the 12 offices in a university-affiliated primary care network in Northern California. Study activities occurred in participants' homes.

Participants. Billing information was used to identify patients aged 40 years or older with one or more of the following: arthritis, asthma, chronic obstructive pulmonary disease, congestive heart failure, depression, and/or diabetes mellitus. Mailed study announcements and telephone calls were employed to recruit patients with these criteria. Power calculations for the 1-year RCT were based on a minimal clinically important difference (MCID) of 3 points in SF-36 Physical Component (PCS-36) and Mental Component (MCS-36) summary scores, our primary outcomes.(33) We conservatively employed a two-point MCID in calculations, approximating an intervention effect size of 0.2 (small effect).(34) Accounting for possible attrition up to 10%, with alpha 0.05, we estimated 120 participants per group would provide 80% power to detect a two-point difference in scores.

Incidence and Prevalance. Not applicable

Methods

Study design. RCT comparing three groups: HIOH, delivered via six weekly sessions, either in participants' homes or via telephone, versus usual care. The study coordinator screened interested patients for additional eligibility criteria: ability to speak and read English; residence in a private home with an active telephone; adequate eyesight and hearing to participate; and at

least one activity impairment, assessed by the Health Assessment Questionnaire (HAQ)(35) and/ or a score of 4 points or greater on the 10-item Center for Epidemiologic Studies Depression Scale (CES-D).(36) The latter were based on focus groups (32) and discussions with the CDSMP developers. Both indicated that such individuals might be more likely to participate in HIOH than in the original program. A study nurse visited eligible individuals at home to ensure that they were medically stable for participation (all were). The nurse also obtained informed consent, administered the baseline study questionnaire, and implemented randomized allocation in blocks of 12 participants via sealed opaque envelopes containing slips of paper printed with group assignments. Participants received $25 after each scheduled follow-up data collection phone call.

Data sources/collection. Data were collected as part of the RCT, via the methods specified below.

Interventions.

HIOH. The original CDSMP is provided by pairs of non-healthcare professionals or peers who have personal experience with chronic conditions, to groups of 10-15 participants in 6 weekly sessions, using an interactive, participatory format. The overall aim is mastery of fundamental self-management tasks, (37) with frequent opportunities provided to practice and receive feedback on performance. Some specific topics included are exercising safely, coping with difficult emotions, and using cognitive symptom management techniques. HIOH was nearly identical to the CDSMP in content but differed in delivery process. Four peers underwent week-long training to deliver HIOH. Each trained peer provided all six intervention sessions to each of their assigned participants. The same intervention script was employed for both intervention groups. More details regarding HIOH are available from the investigators. The study nurse audited the fidelity of the peers' delivery of the intervention quarterly and provided corrective feedback as indicated. Peers also completed a written log indicating whether and for how long they covered each scripted teaching point.

Usual care (control) group. These participants were initially visited in their home by the study nurse, as with intervention participants, and completed the same telephone questionnaires. They otherwise received care from their usual providers, with no study intervention.

Measures. At baseline, in addition to answering basic sociodemographic questions, participants completed three other questionnaires. The first was the Short Portable Mental Status Questionnaire (range of scores 0-10). (38) Scores of 2 or more suggest at least mild cognitive impairment. The second was the NEO-Five Factor Inventory (NEO-FFI), (39) a well-validated 60-item version of the personality factors (Neuroticism, Extraversion, Openness to Experience, Agreeableness, and Conscientiousness) that constitute the FFM. Cronbach's alphas for the five scales ranged from 0.70 to 0.87 in our sample, quite similar to those observed in previous studies that applied the measure in samples similar to ours. (40-42) The third was a five-item measure of perceived control over chronic illness self-management, developed for this study (Cronbach's α = 0.74), with item stems derived from a previously validated measure. (43) Items included were "How much personal control do you have over your self-management behaviors?" and "To what extent do you see yourself as being capable of self-management?" A 7-point Likert response scale is employed, with a single summary score derived (range 5-35, higher scores = greater perceived control over self-management).

Unless noted, all other measures were administered at baseline, 6 weeks, 6 months, and 1 year. We assessed *illness management self-efficacy*, a measure of the effectiveness of delivery of

the intervention content, using a validated, 33-item measure (Cronbach's $\alpha = 0.96$). (44) Respondents rate their confidence for performing social activities, coping with symptoms, and other tasks on a 10-point Likert scale to yield a summary average score (range 1-10, higher scores = greater self-efficacy).

Self-rated health was primarily assessed using the SF-36. (45) The main study outcomes were the MCS-36 and PCS-36 summary scores. (46) Both were designed so a representative population sample would have a mean score of 50 with a standard deviation (SD) of 10. We secondarily explored intervention effects on the five-item General Health (GH) subscale (47) to facilitate comparisons with prior CDSMP RCTs, all but one (12) of which used similar self-rated health measures. Scores for all three SF-36 measures range from 0 to 100 (higher scores = better health).

Participants also completed two EuroQol (EQ) self-rated health measures. (48) We included the preference-based EQ-5D to facilitate potential cost-effectiveness analyses. Respondents rate problems with mobility, self-care, usual activities, pain/discomfort, and anxiety/depression as of the day of assessment, using a three-category scale (no, some, extreme problems). Responses are summed and converted to a summary index by applying scores from population-based valuation sets. (49) We included the EQ Visual Analog Scale (EQ VAS), because it is more responsive to smaller yet still clinically significant changes than other self-rated health measures. (50-54) Participants indicate their overall health on the day of assessment from 0 to 100 (worst to best imaginable).

We employed several other secondary measures. *Functional ability* was measured using the 20-item HAQ (composite $\alpha = 0.92$). (35) Respondents rate difficulty in performing various activities (e.g., dressing and grooming) on a 4-point Likert scale. Item scores were summed and divided by 60 to yield a total score (range 0-1, higher scores = poorer ability). Depressive symptoms were measured with the 10-item CES-D (composite $\alpha = 0.87$). (36) Though no depressive symptom burden categories exist for chronically ill individuals, prior studies suggest the following: 0-9 (low), 10-14 (moderate), and 15-30 (high). (46-48) *Medication adherence* over the 7 days preceding data collection was assessed using a validated questionnaire. (55, 56) A ratio of pills taken (PT) to pills prescribed (PP) was derived for all medications combined. Finally, *hospitalizations and total healthcare expenditures* were examined through 14 months from baseline. Office and emergency room visits, hospitalizations, and skilled nursing facility stays were ascertained from resource management reports. Expenditures were calculated using Medicare reimbursement formulas (57, 58) and, for medications, manufacturers' average wholesale prices. (59)

Analyses. Stata (version 10.0, StataCorp, College Station, TX) was used for analyses.

1-year outcomes study (Hypothesis 1). We examined intervention effects on outcomes measured at more than one time point using a series of mixed effects linear models for repeated measures.(60) The outcome of interest at each time point was the dependent variable, and study group, time of each outcome measurement (baseline, 6 weeks, 6 months, 1 year), and the interaction between time and study group were the independent variables. The mixed effects model adjusted for nesting of each outcome within each subject via random intercepts. Because we were primarily examining change in outcomes, no fixed baseline covariates were included. For the hospitalization outcome, logistic regression was used, with group as the key independent variable and age, gender, race/ethnicity, education, insurance status, MCS-36, and PCS-36 as covariates. For total expenditures, a generalized linear model was used, employing a gamma distribution and log link, with the same independent variables as for the hospitalization outcome.

Moderator analyses.

Hypothesis 2a. To explore the interaction effects between the personality factors and the intervention, five additional analyses were conducted, one for each of the ive NEO-FFI personality factors. No significant effect of the phone intervention on self-efficacy was observed, so the control and phone groups were combined and compared with the home group for these analyses. Independent variables were time (each of the assessments from baseline to 1 year), treatment arm (home vs others combined), the NEO-FFI personality factors (dichotomized at the median score to facilitate interpretation of interactions), and the interactions among time, assigned group, and personality factors. The mixed effects model adjusted for nesting of self-efficacy measurements within each participant via random intercepts. Analyses used the FFM factors dichotomized at median scores to facilitate interpretation and presentation.

Hypothesis 2b. Please note that analyses regarding depression moderation of self-efficacy enhancement were conducted while the RCT was still in progress and so involve scores to 6 weeks of follow-up (immediately post-intervention). We conducted three separate analyses. In each, the self-efficacy score at 6 weeks was regressed onto baseline self-efficacy, study group, one of the three baseline depression measures [self-reported depression diagnosis (yes/no), CES-D category, or MCS-36 category], and the interaction between study group and the depression measure of interest. We also conducted similar analyses utilizing only CES-D score categories to explore if depressive symptoms moderated the 1-year effects of HIOH on self-reported health.

We also conducted a structural equation model analysis to explore the relationships among the study intervention and baseline and 6-week follow-up self-efficacy and MCS-36 scores. The MCS-36 (as a continuous measure) was used instead of the CES-D, because MCS-36 scores were approximately normally distributed, whereas CES-D scores were skewed. Baseline self-efficacy, baseline MCS-36 score, and assigned study group were treated as exogenous variables. Six-week self-efficacy and MCS-36 were treated as endogenous. Pathways from all exogenous variables to both endogenous variables were included. Baseline self-efficacy and MCS-36 were allowed to co-vary, as were the error terms.

Hypothesis 2c. Please note that, again, these analyses were conducted while the RCT was in progress and so only involve self-efficacy to 6 months of follow-up. To explore the moderating effects between perceived control over self-management and the intervention, analyses were conducted including all possible interactions among time, study group, perceived control, and their main effects. Perceived control was included as a continuous variable in one analysis and trichotomized by tercile in a second (low = 8-25, medium = 26-30, and high = 31-35). The categorical approach was used to explore possible non-linear effects of perceived control over self-management. Because no significant effect of phone-delivered HIOH on self-efficacy was observed, the control and phone groups were combined in these analyses.

Limitations. Most participants were White, female, married, and well educated, so the extent to which our findings generalize to others is unclear. However, in CDSMP studies involving less-well-educated minority participants, findings were similar to ours. (7-9, 11, 12) It is also possible that many individuals with the least favorable baseline status of the study outcome variables did not volunteer for this study. Participant drop-out was greater in the intervention groups, presumably reflecting the greater burden of their participation. Finally, the moderator analyses were exploratory, and their findings should be interpreted as such.

Results

Principal Findings. Compared with control, in-home (but not telephone) HIOH led to significantly better illness management self-efficacy at 6 weeks and 6 months and significantly better scores on a secondary measure of self-rated health (EQ VAS) at 1 year but was not effective in improving the primary or other secondary outcomes. Moderator analyses revealed that the self-efficacy enhancing effects of HIOH occurred primarily in those with a particular baseline personality profile (high Neuroticism and/or low Conscientiousness, Agreeableness, and/or Extraversion); higher levels of depressive symptoms (also predictive of 1-year effects of on self-rated health); and lower baseline perceived control over illness self-management.

Outcomes. The **Figure** shows the flow of participants through the RCT. Other than sessions missed by early dropouts, 100% of HIOH intervention sessions were completed. Sixty-one (38 family physicians, 23 general internists) of the approximately 70 primary care providers in the 12 participating primary care network offices had at least one patient (range 1-25) enroll in the study. **Table 1** summarizes participants' baseline characteristics. Randomization equilibrated intervention groups on disease management self-efficacy, personality, and other factors.

Table 2 summarizes main study outcomes by group.

Illness management self-efficacy. The home group had significantly higher mean scores than the other groups at 6 weeks [effect size (change score/standard deviation) vs. control = 0.27, 95% confidence interval (CI) = 0.10, 0.43; p = 0.001; effect size vs. phone = 0.22, 95% CI = 0.05, 0.38, p = 0.01]. The significant differences persisted at 6 months, though with attenuation (effect size vs. control = 0.17, 95% CI = 0.01, 0.33; p = 0.04; effect size vs. phone = 0.17, 95% CI = 0.00, 0.34; p = 0.05), and were no longer present at 1 year.

*Self-rated health***.**

PCS-36, MCS-36, and GH subscale of SF-36. There were no significant differences among groups in PCS-36, MCS-36, or GH subscale scores at 1 year. At no point were the scores for either intervention group significantly higher than for controls.

EuroQol measures. There were no significant effects on EQ-5D scores. There was a significant overall effect of the intervention on EQ VAS score (chi-square = 13.10, degrees of freedom = 6; p = 0.04). Home group scores were higher than in the control group at 6 weeks (effect size = 0.41, 95% CI = 0.15, 0.67; p = 0.002), 6 months (0.31, 95% CI = 0.05, 0.57; p = 0.02), and 1 year (0.40, 95% CI =0.14, 0.66; p = 0.003) and higher than those in the phone group at 1 year (0.30, 95% CI = 0.03, 0.56; p = 0.03).

Other outcomes. There were no significant differences between groups in HAQ scores (functional ability), CES-D scores (depressive symptoms), PT/PP ratios (medication adherence), hospitalizations, or total healthcare expenditures at any follow-up point.

Moderator analyses.

Personality factors. Mixed models testing FFM factor by treatment interactions revealed significant moderating effects on intervention effectiveness of Neuroticism (X2 (5) = 17.5, p =.004) and Conscientiousness (X2 (5) = 19.0, p =.002). The interaction effects for Extraversion and Agreeableness were not significant. The results of the significant effects observed in regression analyses indicated the intervention was effective only in those with high Neuroticism, low Agreeableness, low Conscientiousness, and/or low Extraversion. These effects attenuated over the course of 1 year. No significant main or interaction effects were observed for Openness.

Depressive symptoms. In all three regression analyses, each using self-efficacy at 6 weeks as the dependent measure, there were significant moderating effects of the depression measure on the intervention such that intervention was effective primarily in those with self-reported depression (interaction effect F = 8.24, p = 0.0003), high depressive symptom score (CES-D) (interaction effect F = 5.68, p = 0.0037), and lowest tercile of the MCS-36 (interaction effect F = 4.36, p = 0.0135). In structural equation model analyses, baseline self-efficacy exhibited significant effects on 6-week self-efficacy (t = 17.16) and MCS-36 (t = 4.80), whereas baseline MCS-36 exhibited significant effects only on 6-week MCS-36 (t= 11.83), though its effects on 6-week self-efficacy were not significant. The home intervention (compared with control) significantly improved 6-week self-efficacy (t = 3.22) and 6-week MCS-36 (t = 2.48), whereas the phone intervention had no significant effect on 6-week self-efficacy or MCS-36.

Regarding depression moderator analyses of 1-year HIOH effects, the composite sample median CES-D score (all data collections combined) was 9. Among individuals with scores greater than 9 (moderate or greater symptoms), in-home HIOH was significantly more effective than control in improving PCS-36 scores at 6 months (3.1, 95% CI = 0.3, 5.9; p = 0.03) and 1 year (3.0, 95% CI = 0.1, 5.8; p = 0.04). Similar findings were noted for the EQ VAS at 6 weeks (effect size = 0.57, 95% CI = 0.12, 1.03; p = 0.01) and 1 year (0.55, 95% CI = 0.09, 1.01; p = 0.02). However, there was no significant interaction between CES-D level, intervention group, and time in either analysis. There were no significant intervention effects on other outcomes for individuals with CES-D scores above 9.

Perceived illness self-management control. The mixed effects model including the perceived control/intervention interaction as a continuous variable revealed a significant moderating effect of perceived control (Wald test, chi-square = 13.4, df = 4, p = 0.009), such that the intervention was more effective in enhancing self-efficacy at 6 months in those with lower perceived control. This finding was also confirmed in an analysis treating perceived control as a categorical variable, divided by terciles.

Intervention characteristics. Peers' written logs indicated 100% coverage of scripted topics for all six encounters in both intervention groups. However, the mean minutes per encounter was shorter for the telephone group (64.0, SD 11.9) than for the home group (73.5, SD 15.1). Mean ratings of the overall usefulness of HIOH were similarly favorable in both groups (1.92, SD 0.97 home; 1.91, SD 0.82 phone).

Discussion. Our findings echo and expand upon prior CDSMP studies. We found a significant overall effect of in-home (but not telephone) HIOH on a secondary self-rated health measure, the EQ VAS, at 1 year. However, there were no significant effects of in-home HIOH at any follow-up point on PCS-36 or MCS-36 scores, our primary outcomes, or other secondary outcomes. Finally, there were no significant effects of telephone HIOH at any time. The only other 1-year RCT of the CDSMP, involving an internet variant, found a small effect on health distress but no effects on self-rated health, functional ability, or utilization at 1 year.(10)

The single prior CDSMP study to employ the PCS-36 and MCS-36 measures also found no effects.(12) Thus, the CDSMP may not have large and/or general enough effects to register change on multi-trait self-rated health scales. Prior studies instead found improvements in the energy/fatigue, social role/activities, and health distress subfacets of health status.(5-11)

We secondarily explored effects of HIOH on the SF-36 General Health (GH) subscale, because it is more like the self-rated health measures employed in all but one (12) of the prior RCTs of the CDSMP than are the multi-trait PCS-36 and MCS-36. Again, we found no effects.

Only some prior studies found significant yet small improvements in such measures at 4-6 months, (6, 7, 9, 11) and the 1-year internet RCT found no improvements. (10) The inconsistent, small, 4- to 6-month effects on these self-rated health measures may reflect differences in study populations and/or program implementation and/or chance effects due to multiple testing. Given the lack of 1-year effects of HIOH on our other self-rated health measures, the effect on EQ VAS we found may reflect its greater sensitivity or again, could, represent a chance finding.

Effects of the CDSMP on utilization have also been mixed, with a small reduction in hospitalizations at 4-6 months in a minority of studies.(6, 7) The 1-year internet RCT found no effect on hospitalizations,(10) consistent with our results.

We found a significant effect of in-home HIOH on illness management self-efficacy post intervention, with an effect size comparable to that in prior CDSMP studies. Thus, it is unlikely that the lack of robust effects of in home HIOH on most outcomes stemmed from unsuccessful implementation of the intervention. The group format of the original CDSMP may provide unspecified benefits beyond 1-to-1 delivery, but such a hypothesis remains to be tested.

It is unclear why telephone HIOH had no effects. The same script and peers were employed as for in-home HIOH, and fidelity assessments and participant feedback were equally favorable. However, the mean session time was significantly shorter in the phone group. Thus, delivery of scripted content differed by communication medium. A more powerful therapeutic alliance may also have resulted from face-to-face interaction with peers.

Conclusions. Our project involved the first 1-year RCT of a face-to-face variant of the CDSMP; prior RCTs of the program lasted 4-6 months. We found that in-home (but not telephone) HIOH was effective in improving illness management self-efficacy at 6 months and scores on a secondary measure of self-rated health at 1 year. However, neither intervention had significant effects on the primary or other secondary outcomes at 1 year.

Significance. Our study adds substantially to the existing research literature on the CDSMP, which suggests that the program results in small to moderate and relatively short term (4-6 month) effects, primarily on subfacets of health status and, possibly, acute care utilization. Based on our study, and the prior internet variant study, 1-year effects appear much more limited, though neither RCT involved the original face-to-face, group format program. The findings of our 1-year “main” analyses have been submitted for publication in a manuscript currently under peer review. We have also summarized in three manuscripts, two published articles (#3 and #4 under “List of Publications and Products”), and one manuscript under peer review, the results of the first analyses to explore potential moderators of the effects of the CDSMP. The findings suggest that there are several promising potential moderator variables that could readily be assessed in the clinical setting to help target the program to those most likely to respond. Doing so might strengthen the short and/or long-term effects of the program.

Of note, we have also published the results of two additional analyses from this data set (#1 and #2 under “List of Publications and Products”). The background and methods have not been presented in this report due to space limitations and because they are only peripherally related to the main proposal objectives. In the first, we examined the retest reliability and predictive validity of three different types of self-report adherence measures.(56) We found that self-report pills taken/pills prescribed (PT/PP) and more general medication adherence tendencies measures each tap different behavioral constructs and that self-reported PT/PP at a given point in time is not necessarily representative of medication adherence over time. We also found that 3-4 day recall of PT/PP yields adherence estimates that are practically as reliable

and valid as longer intervals and which predict functional outcomes.

In the second analysis, we examined whether FFM personality factors predicted missing data in our RCT. (61) We found that higher levels of Agreeableness, Conscientiousness, and Openness were independently associated with less missing data. Accuracy of a missing data prediction model also increased significantly when personality variables were added. Thus, assessing personality routinely in clinical studies could inform efforts to maximize data completion and adjust analyses for bias due to missing data.

Finally, two other analyses, again peripheral to our main objectives, have also been conducted. Their findings have been summarized in manuscripts currently under peer review.

Implications. Additional studies are needed to determine whether or not wider application of peer self-management training programs, such as the CDSMP and its variants, would be likely to improve long-term quality of care for people with chronic conditions. Studies to examine which elements of the multi-component CDSMP most influence outcomes and to explore the utility of "booster" sessions may be helpful in achieving stronger and/or more sustained effects. The impact of the program might also be maximized by additional work regarding its effect moderators. For example, in exploratory analyses, we found modest yet persistent effects of HIOH on PCS-36 scores at 1 year among individuals with more depressive symptoms. Thus, adequately powered RCTs that stratify participants by depressive symptoms (or the other putative moderators we examined, personality factors and perceived control over self-management) appear warranted to better examine this issue. Finally, there is considerable (though by no means complete) overlap among the various moderator variables (personality factors, depression, perceived control) that we explored. It is possible the various measures each tap a different facet of some larger "super construct" that influences receptiveness and responsiveness to healthcare interventions. Future studies might examine this issue in more detail.

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Table 1. Characteristics of participants

Characteristic	Home (n = 138)		Phone (n = 139)		Usual care (n=138)	
Age, years, mean (SD)	59.8	(11.2)	61.2	(11.6)	60.1	(11.7)
Gender, number (%)						
Female	108	(78)	109	(78)	104	(75)
Race/ethnicity, number (%)						
Non-Hispanic White	103	(75)	110	(79)	115	(83)
Black	20	(15)	11	(8)	15	(11)
Other	14	(9)	14	(10)	7	(5)
Declined to answer	1	(1)	4	(3)	1	(1)
Education level, number (%)						
High school or less	19	(14)	20	(14)	22	(16)
Some college	53	(38)	50	(36)	58	(42)
College graduate or greater	66	(47)	65	(47)	57	(41)
Declined to answer	0	(0)	4	(3)	1	(1)
Income level, number (%)						
< 40,000	41	(30)	42	(31)	44	(32)
40,000-79,999	42	(30)	37	(27)	43	(31)
≥ 80,000	22	(16)	27	(20)	22	(16)
Declined to answer	33	(24)	33	(24)	29	(21)
Married, number (%)	79	(57)	79	(57)	76	(55)
Chronic conditions, number (%)						
1	55	(40)	72	(51)	43	(31)
2	51	(37)	40	(29)	65	(47)
3	18	(13)	21	(15)	21	(15)
≥ 4	14	(10)	6	(4)	9	(7)
Self-reported diagnoses, number (%) [a]						
Arthritis	83	(60)	73	(52)	77	(55)
Depression	59	(43)	64	(46)	70	(51)
Diabetes	64	(46)	50	(36)	58	(42)
Asthma	34	(25)	25	(18)	39	(28)
Chronic lung disease	15	(11)	11	(8)	17	(12)
Congestive heart failure	17	(12)	17	(12)	14	(10)

Table 1. Characteristics of participants (continued)

Characteristic	Home (n = 138)		Phone (n = 139)		Usual care (n=138)	
Uninsured, number (%)	3	(2)	5	(4)	2	(2)
Perceived control over illness self-management, mean (SD)	27.3	5.7	26.2	6.3	27.8	6.0
NEO-FFI, mean (SD)						
Neuroticism	20.6	9.9	22.1	8.9	21.9	9.6
Extraversion	25.9	8.0	26.1	6.9	25.9	7.6
Openness	28.2	6.6	28.6	6.3	28.9	6.3
Agreeableness	34.4	4.8	33.3	5.6	33.3	5.7
Conscientiousness	31.3	7.5	32.0	6.4	31.9	6.7
Baseline status of outcomes, mean (SD)						
Self-efficacy	7.0	(1.8)	7.0	(1.7)	7.1	(1.8)
PCS-36	33.6	(12.0)	33.3	(12.4)	34.4	(11.0)
MCS-36	45.6	(14.2)	45.3	(13.7)	45.8	(13.7)
GH	47.2	(22.0)	48.1	(24.9)	50.2	(23.2)
EQ-5D	0.74	(0.18)	0.73	(0.18)	0.75	(0.16)
EQ VAS	64.3	(18.5)	66.6	(19.1)	68.4	(18.6)
HAQ	0.92	(0.68)	0.85	(0.74)	0.82	(0.65)
CES-D	9.5	(7.1)	9.8	(6.5)	9.5	(7.1)

Notes: SD = standard deviation; NEO-FFI = NEO-Five Factor Inventory; PCS-36 = SF-36 Physical Component Summary score; MCS-36 = SF-36 Mental Component Summary score; GH = SF-36 General Health subscale; EQ-5D = EuroQol-5D; EQ VAS = EuroQol Visual Analog Scale; HAQ = Health Assessment Questionnaire; CES-D = Center for Epidemiologic Studies Depression Scale, 10-item version; PT/PP = pills taken/pills prescribed over the 7 days prior to data collection. [a] = percentages exceed 100 because many participants had more than one condition.

Table 2. Six-week, 6-month, and 1-year self-efficacy and primary and secondary outcome scores by group

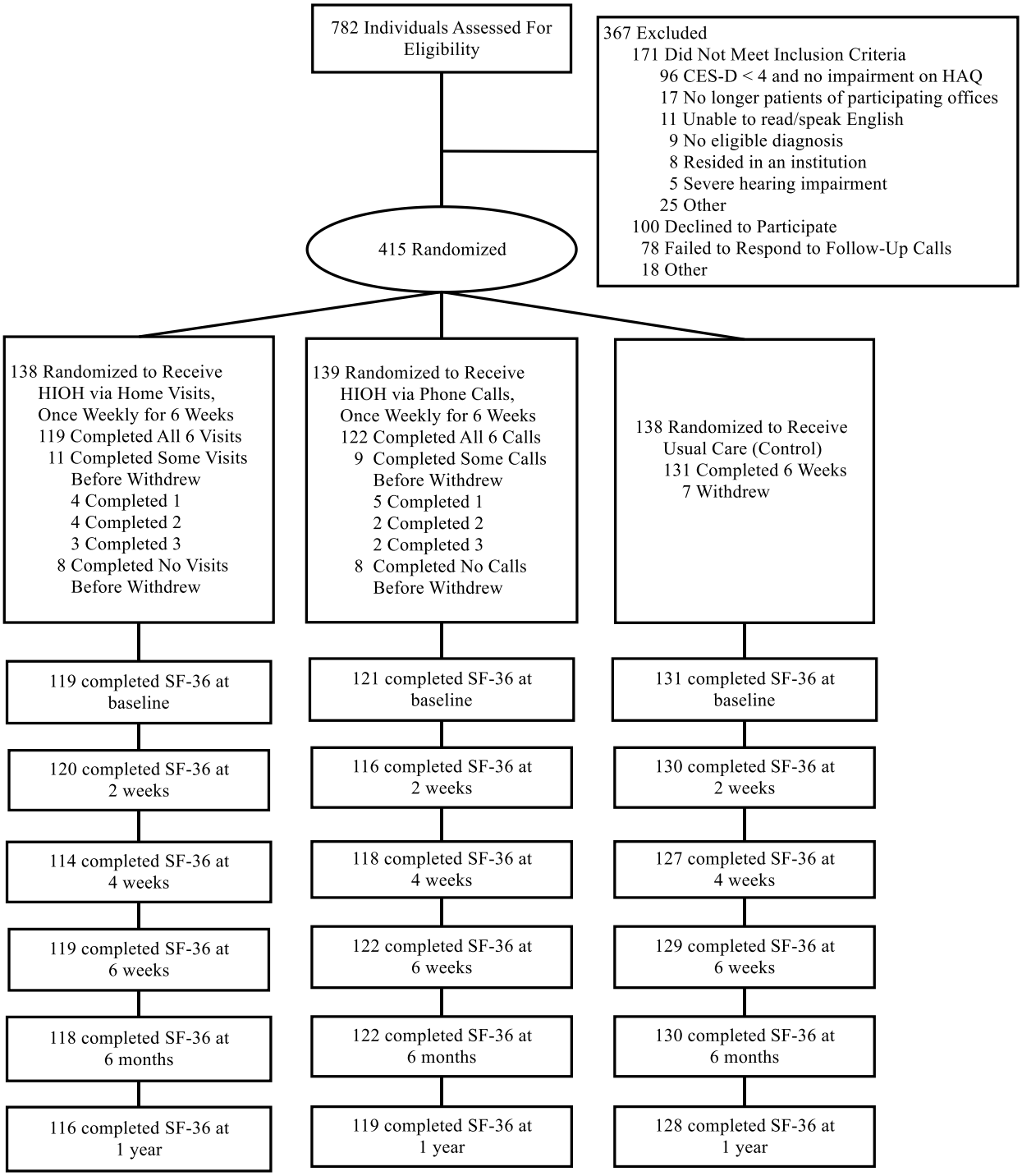
Outcome	Home (n = 138)		Phone (n = 139)		Usual care (n=138)	
Effectiveness of delivery of intervention content						
Self-efficacy, mean (SD)						
6 weeks	7.6	(1.5)	7.2	(1.8)	7.2	(1.9)
6 months	7.5	(1.6)	7.2	(1.8)	7.2	(1.7)
1 year	7.4	(1.6)	7.3	(1.7)	7.2	(1.8)
Primary outcomes						
PCS-36, mean (SD)						
6 weeks	34.9	(11.9)	36.3	(11.6)	37.3	(11.1)
6 months	36.2	(12.0)	37.5	(11.8)	37.2	(11.4)
1 year	35.1	(12.2)	36.4	(12.3)	37.0	(11.6)
MCS-36, mean (SD)						
6 weeks	51.6	(12.1)	48.9	(12.3)	48.6	(12.8)
6 months	49.6	(13.7)	46.1	(13.6)	48.0	(13.0)
1 year	51.2	(12.1)	48.3	(12.0)	48.5	(12.9)
Secondary outcomes						
GH, mean (SD)						
6 weeks	54.1	(21.4)	54.4	(23.4)	54.6	(25.0)
6 months	53.8	(22.5)	53.5	(23.5)	54.4	(25.0)
1 year	54.2	(23.1)	54.3	(22.9)	54.2	(24.1)
EQ-5D, mean (SD)						
6 weeks	0.80	(0.17)	0.80	(0.17)	0.80	(0.17)
6 months	0.82	(0.16)	0.81	(0.18)	0.80	(0.20)
1 year	0.79	(0.18)	0.77	(0.20)	0.81	(0.17)
EQ VAS, mean (SD)						
6 weeks	75.7	(18.5)	73.5	(18.9)	72.4	(19.7)
6 months	74.6	(17.5)	73.0	(20.4)	72.9	(18.9)
1 year	75.7	(15.2)	72.3	(20.1)	72.3	(18.9)
HAQ, mean (SD)						
6 weeks	0.89	(0.70)	0.84	(0.71)	0.76	(0.64)
6 months	0.88	(0.67)	0.85	(0.74)	0.80	(0.68)
1 year	0.91	(0.71)	0.85	(0.71)	0.77	(0.64)

Table 2. Six-week, 6-month, and 1-year self-efficacy and primary and secondary outcome scores by group (continued)

Outcome	Home (n = 138)		Phone (n = 139)		Usual care (n=138)	
Secondary outcomes (cont.)						
CES-D, mean (SD)						
6 weeks	7.1	(6.0)	7.6	(5.4)	8.3	(6.5)
6 months	7.5	(5.9)	9.2	(6.5)	8.2	(6.6)
1 year	7.4	(6.3)	8.6	(6.1)	8.2	(6.9)
PT/PP, mean percentage (SD)						
6 weeks	93	(11)	92	(15)	93	(11)
6 months	91	(16)	89	(18)	93	(13)
1 year	94	(10)	93	(12)	91	(15)
Health care utilization, 1 year						
Hospitalization, %	16	--	11	--	15	--
Expenditures, $, mean (SD)	14,105	(20,279)	12,422	(14,241)	11,493	(10,972)

Notes: SD = standard deviation; PCS-36 = SF-36 Physical Component Summary score; MCS-36 = SF-36 Mental Component Summary score; GH = SF-36 General Health subscale; EQ-5D = EuroQol-5D; EQ VAS = EuroQol Visual Analog Scale; HAQ = Health Assessment Questionnaire; CES-D = Center for Epidemiologic Studies Depression Scale, 10-item version; PT/PP = pills taken/pills prescribed over the 7 days preceding data collection

Figure


782 Individuals Assessed For Eligibility
367 Excluded
171 Did Not Meet Inclusion Criteria
96 CES-D < 4 and no impairment on HAQ
17 No longer patients of participating offices
11 Unable to read/speak English
9 No eligible diagnosis
8 Resided in an institution
5 Severe hearing impairment
25 Other
100 Declined to Participate
78 Failed to Respond to Follow-Up Calls
18 Other
415 Randomized
138 Randomized to Receive HIOH via Home Visits, Once Weekly for 6 Weeks
119 Completed All 6 Visits
11 Completed Some Visits Before Withdrew
4 Completed 1
4 Completed 2
3 Completed 3
8 Completed No Visits Before Withdrew
139 Randomized to Receive HIOH via Phone Calls, Once Weekly for 6 Weeks
122 Completed All 6 Calls
9 Completed Some Calls Before Withdrew
5 Completed 1
2 Completed 2
2 Completed 3
8 Completed No Calls Before Withdrew
138 Randomized to Receive Usual Care (Control)
131 Completed 6 Weeks
7 Withdrew
119 completed SF-36 at baseline
120 completed SF-36 at 2 weeks
114 completed SF-36 at 4 weeks
119 completed SF-36 at 6 weeks
118 completed SF-36 at 6 months
116 completed SF-36 at 1 year
121 completed SF-36 at baseline
116 completed SF-36 at 2 weeks
118 completed SF-36 at 4 weeks
122 completed SF-36 at 6 weeks
122 completed SF-36 at 6 months
119 completed SF-36 at 1 year
131 completed SF-36 at baseline
130 completed SF-36 at 2 weeks
127 completed SF-36 at 4 weeks
129 completed SF-36 at 6 weeks
130 completed SF-36 at 6 months
128 completed SF-36 at 1 year

List of Publications and Products

Journals

1. Jerant AF, Chapman BP, Duberstein P, et al. Is personality a key predictor of missing study data? An analysis from a randomized controlled trial. *Ann Fam Med* 2008; in press.

2. Jerant AF, DiMatteo MR, Arnsten J, et al. Self-report adherence measures in chronic illness: retest reliability and predictive validity. *Med Care* 2008; in press.

3. Jerant AF, Moore-Hill M, Lorig K, et al. Perceived control moderated the self-efficacy enhancing effects of a chronic illness self-management intervention. *Chronic Illness* 2008; in press.

4. Jerant AF, Kravitz RL, Moore-Hill M, et al. Depressive symptoms moderated the effect of chronic illness self-management training on self-efficacy. *Med Care* 2008;46:523-31.

5. Jerant AF, von Friederichs-Fitzwater MM, Moore-Hill M. Patients' perceived barriers to active self-management of chronic conditions. *Patient Educ Couns* 2005;57:300-7.

Electronic Resources and Nonprint Data

6. Jerant AF (presenter), Lorig K, Moore-Hill M, Franks P. Randomized controlled trial of a home-based, peer coach-led chronic illness self-management intervention. North American Primary Care Research Group Annual Meeting; 2007 Oct 20-23; Vancouver, British Columbia, Canada. http://www.napcrg.org/app/search07/results.cfm