Can a Box of Mailed Materials Achieve the Triple Aims of Health Care? The Mailed Chronic Disease Self-Management Tool Kit Study

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INTRODUCTION

More than half of adults in the United States live with chronic conditions, and 25\% of adults have two or more chronic conditions (Ward, Schiller, & Goodman, 2014). These conditions affect both quality of life and health care utilization, which affects health care costs. Arthritis is the most common cause of disability (Hootman, Brault, Helmsic, Theis, & Armour, 2005), while heart disease is the most common cause of death in the United States (Centers for Disease Control and Prevention, 2014). People with chronic conditions spend most of their time outside of the health care system. Thus, it is important that they have the knowledge, confidence, and skills to manage their conditions on a day-to-day basis.

From our experience with both small-group and online programs, it appears that people have definite

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preferences for how they receive self-management education. To this end, we developed the Mailed Chronic Disease Self-Management Tool Kit (subsequently referred to as the Tool Kit) as a third possible mode of self-management education. Self-management materials are delivered through a onetime mailing. We report on the effectiveness of the Tool Kit in a 6-month longitudinal study.

**Background and Rationale**

Over the past two decades, the Stanford Patient Education Research Center has developed and evaluated self-management programs for people with chronic conditions and with comorbid conditions. These include the small-group Chronic Disease Self-Management Program (CDSMP; Lorig et al., 1999) and the online version, Better Choices Better Health (Lorig, Ritter, Laurent, & Plant, 2006). Both these programs have been effective in randomized trials and in subsequent translation studies (see Brady et al., 2013). Each of these programs has strengths and weaknesses. Both are based on self-efficacy theory (Bandura, 1997). Both are 6-week programs, meaning that all the time devoted to the programs must take place in a relatively short time frame. They both incorporate the participants helping and getting help from each other, either face-to-face or via asynchronous discussion boards. While the Internet program is more self-paced than the small-group program in that it is asynchronous, it still requires 2 or more hours per week of participant time. The small-group program requires living near the delivery site and being willing to participate in a face-to-face group. One of its strengths is that it does not require literacy. The Internet program does require literacy as well as a computer and Internet connection. Its advantage is that it maintains the strength of group process and can be taken anywhere and at any time there is a computer and Internet connection. The cost per participant of the Internet program is approximately one third less than the small-group program.

Both these programs have been widely replicated with the CDSMP having reached more than 500,000 people in over 30 countries. Better Choices Better Health, a newer program (see http://patienteducation.stanford.edu/internet/healthyliving.html and http://www.ncoa.org/improve-health/chronic-conditions/better-choices-better-health.html), has reached approximately 10,000 people in the United States, England, Canada, and Australia (Lorig et al., 2008; Lorig et al., 2013; Lorig, Laurent, Plant, Krishnan, & Ritter, 2014). It is currently being trialed in Spain. Despite these numbers, the reach of the programs has been limited in comparison to the numbers of people with chronic conditions. If we are to reach a large percentage of the chronically ill population, we need to expand the modes by which programs are offered. The Tool Kit was developed to reach those people who either could not or preferred not to participate in either online or in-person groups. The kit is composed of several written and audio materials delivered in a onetime mailing (see details below). A similar Arthritis Self-Management mailed Tool Kit program was previously developed and studied with both English and Spanish speakers (Goepinger et al., 2009). In a randomized trial, users of the kit, compared to usual-care controls, had significant improvements over 9 months in communication with physician, health distress, activity/role limitation, disability, depression, pain, fatigue, aerobic, and range-of-motion exercise and arthritis self-efficacy. There were no significant changes in health care utilization and self-reported health (Goepinger et al., 2009). The current program is both (1) a modification and translation of the small group (Lorig et al., 1999) and the online CDSMPs (Lorig et al., 2006) to a third mode of delivery and (2) a modification and translation of the Arthritis Tool Kit to a generic Mailed Chronic Disease Self-Management Tool Kit.

Based on the results from the Arthritis Tool Kit program, we hypothesized that people receiving the Mailed Chronic Disease Self-Management Tool Kit would demonstrate improvement in the health care triple aims (Berwick, Nolan, & Whittington, 2008):

1. Improved care (communications with health care providers and medication adherence)
2. Improved health (lessening of symptoms, fewer unhealthy days, and for people with diabetes, lessening symptoms of hypoglycemia and improved A1C [glycated hemoglobin])
3. Less health care utilization

In addition, we hypothesized that there would be improvements in two behaviors: minutes of aerobic exercise and minutes of stretching/strengthening exercise.

We also conducted exploratory analyses to determine if some categories of participants benefited more than others.

> **METHOD**

**Intervention**

The intervention is based on self-efficacy theory (Bandura, 1997) and integrates three of the four
mechanisms of enhancing self-efficacy. Skills mastery is encouraged through the encouragement of action planning. Modeling is demonstrated by the images in both the book and the voices on the exercise and relaxation tapes. Models and voices are both male and female and represent the major racial and ethnic groups in the United States. Reinterpretation is encouraged as the book discusses multiple causes for various symptoms and offers suggestions of various healthful practices to help mitigate symptoms. We also encourage self-tailoring by offering the opportunity for participants to take a self-test and score it. Based on the score, there are suggestions of how each participant may want to use the Tool Kit materials.

The following materials were sent through the U.S. mail in a box with the study logo:

- A paper-and-pencil self-test scored by participants: For each scale, there was an interpretation with suggestions on how the individual participant could use the Tool Kit. For example, if they were not exercising, the interpretation sheet pointed them toward the exercise CD and exercise chapters in the book (Living a Healthy Life With Chronic Conditions; Lorig et al., 2012). If they scored high on a visual numeric pain scale, then they were pointed toward the chapter on pain as well as the relaxation CD. The scales on the self-test were similar to the study questionnaire.
- A copy of the book (Lorig et al., 2012): If people were visually impaired or had low literacy, an audio CD of the book was available. The book is written at about a seventh-grade level.
- An exercise CD with flexibility and strengthening exercises at three intensity levels: This is designed specifically for people with chronic conditions.
- A relaxation CD with three different relaxation exercises (two guided imagery and a body scan).
- Eight tip sheets, one for each major tool such as managing pain, managing sleep, and so on: These have the same content as the book but in bullet point, lower literacy format (fifth-grade level).

The subject matter and content of the tip sheets were determined based on a modified Delphi process (Hsu & Standford, 2007) conducted on the Internet with small-group CDSMP master trainers. Approximately 400 trainers participated.

All procedures, including the informed consent process, the intervention, the study, and the testing of A1C, were conducted in accordance with the ethical standards and were approved by the Stanford School of Medicine Institutional Review Board (aka the Administrative Panels for the Protection of Human Subjects). All data used for analyses were maintained on computers in deidentified form, and all researchers involved in recruitment, data collection, and analyses were trained and certified in the protocols of the Health Insurance Portability and Accountability Act. The study was registered at clinicaltrials.gov as trial NCT01832064.

Participants

Participants were recruited by asking the current CDSMP small-group master trainers (N = approximately 1,400) to advertise the program in their organizations as well as by approximately 8,000 e-mail mails sent out by OASIS, an educational program for seniors. Advertising materials invited interested potential participants to call Stanford’s toll-free number. Eligible participants had to live in the United States, have one or more chronic conditions, not have been in cancer treatment for the past year, and not have taken any Stanford self-management program. After screening for eligibility callers were mailed enrollment packets with consent forms and a baseline questionnaire. Participants who consented and completed the questionnaire were mailed the Tool Kit. Recruitment was completed in approximately 2 months.

Participants who indicated they had been diagnosed with Type II diabetes were also asked to consent to providing two A1C samples—one at baseline and one at 6 months. Those consenting were sent home A1C capillary blood sampling kits. The blood samples, identified only by number, were then mailed to CoreMedica Laboratories (https://www.coremedica.net/), a CLIA certified lab, which returned the results to the investigators with the numeric code. Consents for the A1C sub-study and for procedures protecting A1C samples were approved by the Stanford Institutional Review Board.

At 6 months, all participants were mailed a follow-up questionnaire. In addition, they were mailed a two-page survey of their usage of the Tool Kit and how useful they found those tools. Participants not returning the survey were sent post card reminders, called, and finally sent second questionnaires.

Measures

There were three health care outcome measures, six health indicator measures plus two additional measures for participants with diabetes, three health care utilization measures, and two health behavior measures. All measures were self-report.

Health Care Measures. Medication Adherence was the sum of four questions regarding medication use (Morisky, Green, & Levine, 1986). Communication with physicians...
was measured using a three-item, 6-point scale. This instrument was developed and validated by the Stanford Patient Education Research Center during previous studies (Lorig et al., 1996). Scores range from 0 (never engage in the three behaviors; e.g., “discuss personal problems related to your illness”) to 5 (always do all three behaviors). A higher score indicates more communication. Confidence in completing medical forms consisted of a single item ranging from 0 (not at all confident) to 4 (extremely confident). Chew et al. (2008) found this single item to be predictive of health literacy.

Health Indicators. Self-reported health is a single-item measure from the National Health Survey that is predictive of future health status (Idler & Angel, 1990). It has a test–retest reliability of .92. Health interference with social roles was measured using the Social/Role Activity Limitations Scale, which is a four-item scale (Lorig et al., 1996). Values range from 0 (health problems do not interfere with activities) to 4 (almost total interference). Depression was measured by the Patient Health Questionnaire Depression (PHQ-8) scale (Kroenke et al., 2009). PHQ-8 scores range from 0 to 24 with a higher score indicating more depression. Number of days of poor physical health, poor mental health, and physical or mental health prevented participation in normal activities in the past month were adapted from the Behavioral Risk Factor Surveillance System Survey (Centers of Disease Control and Prevention, 2011). In addition to the A1C home test kits described above, participants with diabetes were asked to complete a seven-question symptoms-of-hypoglycemia scale (Piette, 1999) with a range of 0 to 6.

Health Care Utilization. Medical utilization (e.g., physician visits, emergency department visits, and nights in the hospital) over the prior 6 months was measured by self-report. In a study evaluating the validity of self-reported utilization compared to utilization reported by chart audit (Ritter, Kaymaz, Stewart, Sobel, & Lorig, 2001), there were consistent relationships (slight underreporting) and no bias toward improved reporting over time.

Health Behaviors. Instruments measuring minutes of aerobic exercise and of stretching and strengthening exercise (range of motion) in the past week were developed and validated by the Stanford Patient Education Research Center during previous studies (Lorig et al., 1996).

The Tool Kit usage survey consisted of 5 question regarding usage of the tools, 1 visual numeric question on overall usefulness of the Tool Kit, and 13 questions regarding the usefulness of the specific tools. This survey was developed for this study.

**Data Analyses**

Outcomes at 6 months were compared to baseline using paired t tests. Those who completed 6-month questionnaires were compared to noncompleters (“dropouts”) at baseline using independent sample t tests. For the smaller sample of those with diabetes and baseline A1C tests above 7.0, changes in A1C and the hypoglycemic index at 6 months were evaluated using paired t tests.

To explore differences by subgroup, we used independent sample t tests to compare 6-month change scores on all outcome variables. Comparisons were made between the following dichotomized groups: African American versus non–African American, males versus females, older (age 61+) versus younger, and more educated (16 years+) versus less educated. Because the most frequent self-reported disease was arthritis and more than 40% of the population scored 10 or above on the PHQ-8, we also conducted comparisons for those two subgroups. We were interested in depression because of the relatively high mean PHQ-8 depression scores (see Results section), while arthritis was of special interest in part because of the previous success of the Arthritis Tool Kit. For age and education, the median was chosen to separate groups; for PHQ-8, a value of 10 is considered indicative of clinical depression (Kroenke et al., 2009).

From the Tool Kit usage survey, we computed two measures of usage. First, we computed a dichotomous variable consisting of whether participants used any part of the Tool Kit (self-test, Living a Healthy Life book, and the CDs or the tip sheets) versus did not. We compared Tool Kit users with nonusers for each of the 6-month outcome variable change scores using independent sample t tests.

Second, we computed a standardized (0-1) mean of three components of the Tool Kit (the self-test, the book, and the other components). This could range from 0 (did not use or read) to 1 (used the self-test, read most of the book, used each CD and the information tip sheets regularly). We then computed correlation coefficients (Pearson’s r) and p values indicating the association between the usage mean and each of the 6-month outcomes.

We also computed and report the mean usefulness of the overall program and the various components as perceived by the participants.
RESULTS

Participants

Of the 437 potential participants who called expressing interest, 255 completed consent and baseline questionnaires and were mailed the Tool Kit (Figure 1). Of these, 217 (85%) completed 6-month questionnaires and 215 completed a survey on their use of the program. Eighty-seven participants with diabetes consented to A1C testing and 83 of these returned valid A1C test kits. Of these, 38 had A1C of 7.0 or higher and are considered the high A1C group.

The mean age of participants was 59.9 years (range =21-87, SD = 13.2). Ethnically, 75% of participants were White, 14% were African American, 6% reported being mixed, 4% Asian, and 1% were Native American or Alaskan Native. Eighty-four percent of the participants were female. The mean level of education was 15.6 years, (range 9-23, SD = 2.0). The mean number of chronic diseases reported per participant was 3.6 (SD = 2.0), ranging from 1 to 12 conditions. The mode and median was three chronic conditions, and 81% of the participants reported more than one condition. This is higher than the mean of 3.0 found in a national (U.S.) sample of participants in the small-group CDSMP that was conducted recently in 22 states (Ory et al., 2013). Arthritis was the most frequent chronic condition, reported by 58% of the participants. Forty-three percent of the sample scored high (10 or above) on the PHQ-8 depression scale, suggesting clinical depression (Kroenke et al., 2009).

Baseline means for the outcome measures are shown in Table 1. The mean level of PHQ-8 depression was 8.6...
Six-Month Changes

Six-month changes in outcome measures are shown in Table 1. Two of three health care indicators improved significantly (communication with physician and medication adherence) while confidence in completing medical forms did not. All six health indicators had significant improvements (decreases in symptoms) over the 6 months after baseline. Physician visits decreased by a mean 0.65 days in 6 months, while nights in hospitals and emergency department visits did not change significantly. Minutes of stretching/strengthening exercise improved, while aerobic exercise did not increase significantly.

For participants with high baseline A1C, there was no significant change in A1C. Symptoms of hypoglycemia did improve significantly.

Each of the analyses of 6-month changes was then repeated comparing various subgroups (see Supplemental Tables 1-5, available online at http://hpp.sagepub.com/supplemental). There were few significant differences by subgroups. Being less educated was associated with greater improvement in communication with physician ($p = .028$). There were no significant differences between African American and other participants, although African American participants appeared to improve as much as, if not slightly more (nonsignificantly) than, non–African Americans. Those who were depressed compared to nondepressed had significant improvements in medication adherence ($p = .007$) and, as to be expected, PHQ-8 depression scores ($p < .001$). There were also trends for the depressed to have greater reductions in number of days that mental health was not good and number of days health interfered with usual activities ($p = .07$ and $.05$, respectively). Finally, those with arthritis compared to those without arthritis had greater reductions in days that physical health was not good ($p = .007$) and emergency department visits ($p = .020$).

Six-Month “Dropouts” Versus Completers

We compared the baseline scores and demographic variables for the 38 people who failed to complete the...
6-month questionnaire (including the two who died) with those of the 217 completers. There were no statistically significant differences using a wide range of variables, although there was a tendency for the non-completers to be more depressed (mean of 10.3 vs. 8.4 on PHQ-8, \( p = .077 \)). African American participants had a 94% follow-up rate compared to 85% for the overall sample (\( p = .088 \)).

**Use of Program and Perceived Usefulness of Program**

On a scale of 0 to 10, from *not at all useful* to very *useful*, the mean reported usefulness of the Tool Kit was 6.5 (SD = 2.7). This score increased to 6.9 (SD = 2.5) when we excluded those who did not use any part of the Tool Kit. The reported usefulness of the program was not significantly correlated with any of the 6-month outcome change scores. Among the different components of the kit, participants reported the book as the most useful (mean of 2.41 on a 1 to 3 scale from *not useful* to very *useful*), followed by healthy eating tip sheet \( (M = 2.33) \) and mind–body connection tip sheet and the self-test \( (M = 2.26) \). The component reported least useful was the exercise CD \( (M = 1.92) \).

Twenty-nine of the participants (13%) who returned the usage survey reported not using any components of the Tool Kit. Among those who reported some usage, 78% used the self-test, 90% the book, 52% the exercise CD, 66% the relaxation CD, and 82% the information tip sheets. Table 2 shows the 6-month outcome changes for those who used the Tool Kit compared to those who did not. There were significant differences in PHQ-8 depression, days mental health not good, and days mental or physical health interfered with usual activities and medication adherence. In each case those who used the Tool Kit had greater improvements at 6 months.

Only two of the 6-month outcome change scores were correlated with the amount of usage of the three Tool Kit components (Table 3). These were PHQ-8 depression and number of days physical or mental health interfered with usual activities. In both cases greater use was moderately associated with less depression or fewer days of health interference. There was also a tendency among the participants with diabetes for greater usage to be associated with less hypoglycemic symptoms \( (r = −.228, \ p = .057) \).

**DISCUSSION**

There were statistically significant 6-month improvements within each of the health care triple aims. Two of three health care indicators (medication adherence and communication with physicians) improved. There were improvements in six of six health indicators. For the subset of participants with diabetes, there were significant improvements in hypoglycemia symptoms but not A1C. There was a significant reduction in physician visits, although emergency department and hospital visits did not change. Overall, the Mailed Chronic Diseases Self-Management Tool Kit appears to be associated with improvements in each of the health care triple aims.

A major reason for developing the Tool Kit was to give people with chronic conditions options for receiving self-management education. All participants volunteered proactively to receive a mailed intervention. The population was a national convenience sample. It is noteworthy that participants had a greater number of chronic diseases and were more depressed than those who participated in the recent national small-group CDSMP evaluation (Ory et al., 2013). Thus, it may be that the Tool Kit is more acceptable or accessible to those who are sicker or more depressed than the small-group CDSMP. The participants here also tended to be younger (59.9 vs. 66.6), more educated (15.6 vs. 13.8 years of education), and less likely to be Hispanic (3.1% vs. 4.9%) than participants in the national small-group CDSMP (Ory et al., 2013). A more detailed comparison between those who choose between different programs should be undertaken in the future.

Unlike many studies where African Americans are underrepresented, in this study, they participated at a slightly high rate than adult African Americans in the general population (14% vs. 13%). These suggests that in addition to reaching a more ill and more depressed population than the small-group CDSMP, the Tool Kit intervention is acceptable to African Americans. Furthermore, both those with greater depression and African Americans appear to have benefited from the intervention at least as well other participants.

Participants with arthritis had outcomes similar to those of people with arthritis who participated in a previous study of the Arthritis Self-Management Tool Kit on which the current Tool Kit is based (Goepfinger et al., 2009). This suggests that people with arthritis can benefit from using an intervention that is not disease-specific. The advantage of an intervention that is applicable to many if not most chronic conditions is that the potential reach is greater and it better serves the needs of those with comorbid condition. These findings are similar to those found when comparing disease-specific and a more generic small-group self-management program for people with arthritis (Lorig, Ritter, & Plant, 2005).

We are often asked about the comparative effectiveness of various modes of self-management education.
Such comparisons are not useful as people have definite preferences about how they wish to learn and participate. Many people will not or cannot use the Internet, others will not or cannot go to small groups, and still others will not or cannot use print and audio materials sent through the mail. To reach the greatest population, we need to offer interventions in multiple modes. A potential future study might randomize participants to receive self-management education via small groups, Internet, mail, or free choice. Such a study would determine the acceptability of each delivery mode, the potential reach of each mode, and the comparative effectiveness of each mode.

**Limitations**

Unlike the previous Arthritis Mailed Tool Kit study, this translation study was not randomized with an intervention and a control group. The lack of baseline differences between those who completed 6-month questionnaires and those who did not and the relatively high follow-up response rate suggest that “dropouts” were not a major source of bias. However, there is the possibility that people with similar diseases would have improved similarly without having been sent the Tool Kit. Although we cannot rule this out, the Arthritis Mailed Tool Kit study included a randomized control group and looked at several of the same variables that improved for participants within this study. In that study, there was almost no change among control participants for self-reported health, PHQ-8 depression, activity/role limitation, and communication with physician (Goeppeinger et al., 2009).

Since the population self-selected to receive the Tool Kit, we cannot assume that those who would prefer an online or small-group program would benefit to the same degree. As suggested above, this would require further study.

**Summary**

Participation in the Mailed Tool Kit Program was associated with 6-month improvements in each of three triple aims of health care: with health indicators and...
health improvements and with reductions in physician visits. Among participants with diabetes, there were improvements in hypoglycemic symptoms but not in hemoglobin A1C. Depression and number of days of health interference were associated with usage of the program, while health behaviors and health care utilization appear to have lower associations with usage of the Tool Kit. The Tool Kit approach offers a third mode, along with small groups and the Internet, to deliver a health care intervention to people with chronic disease. In conclusion, the Mailed Chronic Disease Self-Management Tool Kit appears to assist participants in achieving the triple aims of health care and may be a useful means of assisting people with chronic conditions to receive self-management education.

SUPPLEMENTAL MATERIAL

The online supplemental material is available at http://hpp.sagepub.com supplemental.

REFERENCES


**TABLE 3**

<table>
<thead>
<tr>
<th>6-Month Outcome Variable</th>
<th>Correlation Coefficient (r)</th>
<th>p (r = 0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication adherence</td>
<td>.101</td>
<td>.466</td>
</tr>
<tr>
<td>Communication with physician</td>
<td>−.172</td>
<td>.305</td>
</tr>
<tr>
<td>Confidence in completing medical forms</td>
<td>.063</td>
<td>.370</td>
</tr>
<tr>
<td>Overall general health</td>
<td>−.055</td>
<td>.428</td>
</tr>
<tr>
<td>PHQ-8 depression</td>
<td>−.235</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Activity/role limitation</td>
<td>−.108</td>
<td>.121</td>
</tr>
<tr>
<td>Days physical health not good in last month</td>
<td>−.032</td>
<td>.642</td>
</tr>
<tr>
<td>Days mental health not good in last month</td>
<td>−.103</td>
<td>.141</td>
</tr>
<tr>
<td>Days health interfered with usual activities in last month</td>
<td>−.168</td>
<td>.016</td>
</tr>
<tr>
<td>A1C (high A1C subset, N = 38)</td>
<td>.101</td>
<td>.466</td>
</tr>
<tr>
<td>Hypoglycemia symptoms (high A1C subset, N = 38)</td>
<td>−.228</td>
<td>.057</td>
</tr>
<tr>
<td>Physician visits in past 6 months</td>
<td>.056</td>
<td>.424</td>
</tr>
<tr>
<td>Emergency department visits in past 6 months</td>
<td>.075</td>
<td>.424</td>
</tr>
<tr>
<td>Nights in hospital in past 6 months</td>
<td>.001</td>
<td>.987</td>
</tr>
<tr>
<td>Minutes of aerobic exercise in last week</td>
<td>.052</td>
<td>.453</td>
</tr>
<tr>
<td>Minutes of stretching/strengthening exercise in last week</td>
<td>.129</td>
<td>.064</td>
</tr>
</tbody>
</table>

NOTE: PHQ = Patient Health Questionnaire Depression Scale; AIC = glycated hemoglobin. Correlation coefficients (Pearson’s r) are for mean usage of three Tool Kit components with 6-month outcomes change scores. p values are the likelihood of obtaining a correlation of this size if sampling from a population with zero correlation.


