Research Report

The Effectiveness of Diabetes Self-Management in the Canadian Context

Submitted to

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The Effectiveness of Diabetes Self-Management in the Canadian Context

Executive Summary

This report describes a research study which used a randomized controlled trial to investigate the effectiveness of two types of peer-led self-management programs in bringing about improvements in subjects with type 2 diabetes compared to subjects in a control group who did not take either program. The research questions investigated were: 1) would participation in a self-management program (either the Diabetes or the Chronic Disease Self-Management Program) improve clinical and self-report outcomes; and 2) would there a difference in the effectiveness between the two programs?

The "Background" section provides a historical overview of the development of the Diabetes and Chronic Disease Self-Management Programs, how they were evaluated and their effectiveness. "Subject Recruitment and Randomization" describes how subjects in this study were recruited and randomized into the intervention and control groups. The section describing "Outcome Measures" summarizes demographics, lists the outcome measures used in this evaluation and provides baseline scores for the 30 outcome measures by each group. Statistical tests confirmed that mean outcome scores of subjects in the three study groups at baseline were equivalent. "Description of Analysis" describes the methodology and considerations used to conduct the statistical comparisons.

The first part of the "Results" section provides the findings of the analysis comparing the effects of the intervention on subjects in the intervention groups to subjects in the control group. The findings show that the self-management programs had affected five of the 30 measures: fatigue, cognitive symptom management, self-efficacy with regard to the disease in general, communication with physician, and the score on the Diabetes Empowerment Scale (DES). In addition, three variables – social role limitations, total hospital nights, and Hemoglobin A1C (A1C) – showed marginally significant interaction effects. To examine the five outcome measures where the interaction was statistically significant (plus A1C which was marginally significant and an important measure), the group means are plotted in Figure 2. In the second part of the "Results" section the same type of analysis is described but this time between the Diabetes, the Chronic Disease and the Control groups. The results are quite similar, with four of the five measures remaining statistically significant – fatigue, cognitive symptom management, communication with physician, and diabetes empowerment. Figure 3 shows that there were only a few instances where one type of self-management program was more effective.

The section of "Qualitative Research" describes the findings from two focus group meetings involving study participants. It summarizes their motivation for participating in the study, their experience in the program and outlines their suggestions. The "Implications" section accentuates

how findings from this study can augment the growing international body of evidence concerning the effectiveness of self-management programs. Lastly, the “Dissemination” section lists the ways the report is being shared with the academic and medical communities, several ‘communities of interest’ and organizations implementing self-management programs.

Background

In 1996 the Stanford Patient Education and Research Center developed the Chronic Disease Self-Management Program (CDSMP). This was a general program dealing with the common problems people experience with most chronic health conditions (e.g., pain, fatigue, negative emotions etc.) and therefore appropriate for most chronic health conditions. This self-management program is led by pairs of trained lay leaders to groups of 10 to 16 people once each week for two and one-half hours for six consecutive weeks. The workshops are held in community locations such as community and recreation centres, schools and churches. Each leader successfully completes a four-day training workshop where he/she learns to follow a manual to lead the course. Participants include persons living with chronic health conditions as well as their families, friends and caregivers.

The CDSMP teaches people a variety of necessary skills, namely: problem-solving, decision-making, finding and using appropriate resources, developing patient-provider relationships, and ways to take action. These programs do not take the place of regular patient education but are complementary to and reinforce such education. In these programs people obtain new information, learn new skills and abilities, and develop higher levels of confidence to manage and cope with chronic health conditions. Approximately 75% of participants make plans to exercise and to improve eating habits. In addition to these basic program components, the CDSMP also teaches people: how to develop an exercise program, how to use their mind to manage symptoms, healthy eating strategies, breathing exercises, communication skills, how to use medications effectively and how to deal the emotions of chronic illness such as anger and depression.

The CDSMP was introduced in BC in 1998 and has subsequently has been implemented in all Canadian provinces and territories except Nunavut. The CDSMP has been designated as an evidence-based best practice program (1), and is being delivered in approximately 25 countries. It has been evaluated using randomized controlled trials (2), dissemination studies (3), follow-up and cost-analysis studies (4, 5), and has demonstrated external validity through successful implementation and producing similar results in different countries and with different populations (6-11). As well, the US Centers for Disease Control and Prevention has conducted a meta-analysis of the CDSMP and found that it did produce both small and medium effects on participants' attitudes, behaviours and health status (12).

In 2006 a Spanish version of a Diabetes Self-Management Program (DSMP) was developed by Stanford University. Essentially this program contains many of the strategies and techniques used in the CDSMP but also teaches skills that are required by persons living with diabetes, namely: what diabetes is, monitoring blood glucose, preventing low blood glucose, preventing or delaying complications, planning healthy meals, reading nutrition labels, diabetes specific medications, strategies for sick days, foot care and dealing with stress. The Spanish DSMP was evaluated in 2007 using a randomized controlled trial (13). Participants were followed for one year. The results found that compared to usual-care control subjects, at four months the participants demonstrated

improved health status, health behaviour and self-efficacy, as well as fewer emergency room visits. At one year, the improvements were maintained and remained significantly different from baseline condition.

After successful outcomes were found with the Spanish DSMP, it was translated into English and a randomized controlled study was conducted to assess its effectiveness for English-speaking Americans. The study was completed in 2008 and the results found that at six months, subjects in the experimental group had significant improvements in depression, symptoms of hypoglycaemia, communication with physicians, healthy eating, and reading food labels. At 12 months, participants in the experimental group continued to have improvements in depression, communication with physicians, healthy eating, patient activation, and self-efficacy; however, there were no significant changes in health care utilization measures (14).

In 2008 the Stanford DSMP was implemented in to most Canadian provinces. The status of the DSMP and CDSMP in Canada is as follows:

- Research conducted in the United States found that the DSMP improves patient outcomes at 6 and 12 months;
- There is ample evidence that the CDSMP improves patient outcomes at 6 and at 12 months;
- That participation in a community self-management program enhances outcomes of patients who have already received diabetes patient education.

However, there was still a lack of evidence regarding these self-management programs, namely:

- Will participation in the DSMP improve patients' clinical outcomes, self-efficacy and behaviours in the Canadian context?
- Will participation in either the CDSMP or the DSMP improve health care utilization?
- Is there a difference in effectiveness between the DSMP which has been implemented on a limited basis and the CDSMP which has been widely implemented?

Subject Recruitment and Randomization

Ethical approval for this research was obtained from the University of Victoria Human Research Ethics Committee. Study recruitment began in September 2010 through a variety of daily and weekly newspapers circulated in the Greater Vancouver area. When interested persons responded the study coordinator described what was involved and what their responsibilities would entail if they volunteered. The coordinator also informed them that the programs were available in the community and they did not have to participate in the study to receive the programs. To be included in the study subjects' needed to: complete the consent form; produce the doctor's letter confirming type 2 diabetes and agreement to provide subject's A1C, HDL, LDL, blood pressure, weight, BMI and waist circumference to the researchers at 0, 6 and 12 months; understand and speak English; be at

least 21 years of age; and have type 2 diabetes. Packages were mailed to persons who agreed to participate in the research study (Appendix B).

Training of new program leaders for both programs and course registration and set-up began in January 2011. Both Programs were implemented on a regular basis during the summer and fall of 2011 and throughout 2012. Subjects were informed of programs offered at various times, dates, and locations and could register for the most convenient option. During 2011 and 2012, 39 DSMP programs and 52 CDSMP programs were implemented in the study area.

After completing baseline questionnaires and having their family doctor confirm they had type 2 diabetes, subjects were randomly allocated to a group that received the DSMP, a group that received the CDSMP, or to a group that had not nor would not receive either of the programs for at least 12 months.

Measurements were taken at three points in time: at baseline before randomization, at six- months post program and at twelve-months post program. As subject recruitment and program delivery took place on a continuous basis during 2011 and 2012, the project could not be concluded until December 2013 to ensure 12-month post-program data could be collected from subjects who took a program during 2012.

The study used a 3-arm randomized controlled trial design with clinical measures taken at baseline, 6 and 12 months. Once subjects had signed consent forms, provided a letter from their doctor, and completed the baseline questionnaire, their de-identified study ID number was randomly assigned using a spreadsheet to one of three comparison groups, namely: diabetes, chronic disease and the control group. A block randomization scheme, based on 12 blocks of size 30 was used. For each block, a computer random number generator randomly permuted the 30 IDs into three groups. This ensured a reasonably close balance of the numbers in each group at any time during the trial. Figure 1 illustrates the randomization results. In total, 358 persons met the eligibility criteria and were randomized to one of the three groups. The program and questionnaires at 6 and 12 months were completely by 86 of the 130 subjects assigned to the DSMP group, and 63 of the 109 assigned to the CDSMP group. Several subjects in the CDSMP group withdrew indicating they wanted a program that focussed on diabetes. As well, several persons assigned to the control group indicated they did not want to wait for twelve months to participate in the program.

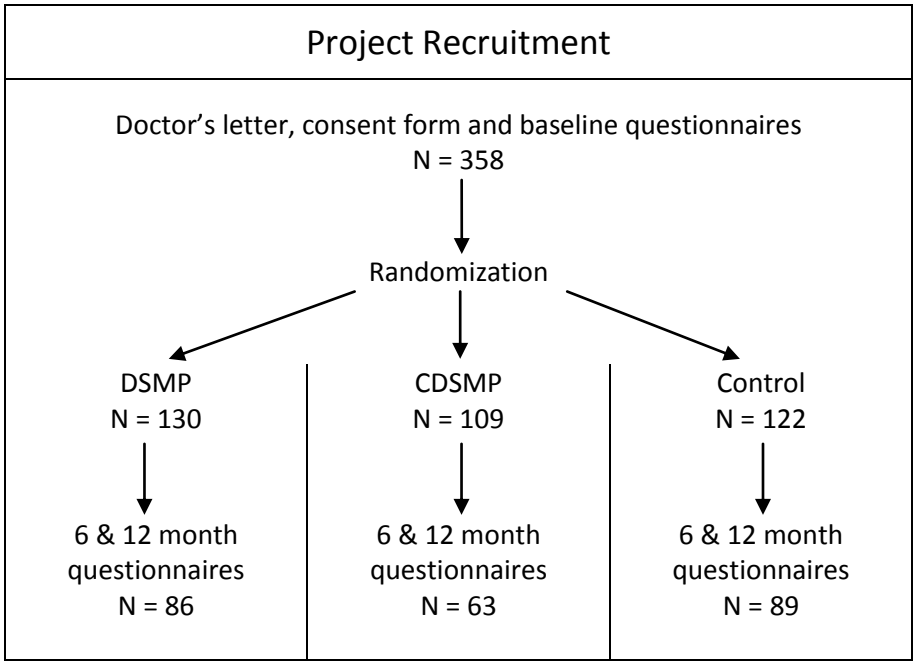

Figure 1. Randomization process and number of subjects in each group completing the study.

In total 238 completed the baseline, 6-month and 12-month questionnaires. Eighty-six persons were allocated to a group that took the DSMP program, 63 persons to a group which took the CDSMP program, and 89 persons to the control group which would not take either program for at least twelve months.

Outcomes Measures

The primary clinical outcome measure was A1C level. Secondary clinical outcome measures were blood pressure, weight, BMI, waist circumference, cholesterol levels, and self-report measures of self-efficacy, attitudes, behaviours, health status and diabetes quality of life. Table 1 shows baseline characteristics of subjects in the three groups and Table 2 shows mean baseline scores on the outcome measures for the three groups.

Table 1. Subjects' baseline information

Variable	DSMP (N=86)	CDSMP (N=63)	Control (N=89)
Mean age	64.6 (SD=9.1, range 47-83)	63.8 (SD=9.5, range 44-82)	63.8 (SD=9.5, range 34-83)
Male (%)	64	54	60
Mean years of education	15.2 (SD=3.2, range 9-22)	14.8 (SD=3.1, range 10-22)	15.3 (SD=3.8, range 7-22)
Mean number of chronic conditions	1.0 (SD=1.8, range 1-4)	2.1 (SD=1.1, range 1-4)	2.1 (SD=1.2, range 1-4)
Living with others (%)	74	67	67
Length of time with diagnosis (yrs)	8.75	8.75	9.5
Received diabetes patient education (%)	81	71	79
Time since attending education centre (yrs)	5	5	5.5
Sessions attended in SM Program	5	5	NA

The self-administered questionnaires inquired about the following:

a) Health status - self-rated health and health distress (15), brief depression (16), social/role activities limitations (17), illness intrusiveness (18), fatigue, shortness of breath and pain severity (17).
b) Diabetes empowerment - the Diabetes Empowerment Scale (DES) (18) is a valid and reliable measure of diabetes psychosocial self-efficacy.
c) Self-efficacy to manage diabetes and self-efficacy to manage disease in general (17).
d) Self-management behaviours - communication with physician, cognitive symptom management, and amount of time walking (17).
e) Medical care utilization in the last six months - number of doctor appointments, number of times hospitalized and nights in hospital.
f) Measurements – A1C, blood pressure, HDL and LDL, weight, body mass index and waist circumference measurements were taken by the subjects' physician.

Table 2 displays the mean and standard deviation of each measure for subjects in the three groups.

Table 2. Baseline scores on outcome measures

Outcome measure	DSMP	CDSMP	Control
Health status			
Self-rated Health (1-5)↓	2.84 (.82)	2.84(.88)	2.89 (.94)
Health Distress (0-5)↓	1.63 (1.22)	1.74(1.18)	1.89(1.28)
Social Role Limitation(0-4)↓	.90(1.00)	.85(.98)	1.02(1.02)
Fatigue (0-10)↓	4.05(2.41)	4.06(2.40)	4.07(2.60)
Shortness of Breath (0-10)↓	1.94(2.20)	1.83(2.41)	1.94(2.24)
Pain (0-10)↓	2.66(2.31)	2.83(2.67)	3.51(3.08)
Diabetes Empowerment	3.74(.51)	3.64(.70)	3.74(.55)
Illness Intrusiveness↓	32.79(14.5)	32.30(15.4)	37.48(17.8)
PHQ-9 Depression↓	5.79(5.20)	5.38(5.41)	6.64(5.99)
Depressive Symptoms↓	8.69(6.18)	8.13(5.47)	9.95(7.01)
Self-management behaviours			
Communication with Physician (0-5) ↓	2.51(1.09)	2.49(1.36)	2.62(1.28)
Cognitive Symptom Management	1.12(.89)	1.04(.72)	1.11(.93)
Self-efficacy			
Self-efficacy to manage symptoms (1-10)↑	6.83(2.32)	7.01(2.63)	6.78(2.63)
Self-efficacy to manage disease (1-10)↑	6.86(2.31)	6.99(2.44)	6.91(2.46)
Health care utilization			
Physician visits/last 6 months	4.52(3.70)	4.76(4.19)	4.72(3.66)
Hospitalizations/last 6 months	.06(.24)	.13(.58)	.11(.35)
Nights in hospital/last 6 months	.13(.65)	.05(.29)	.43(1.87)
Managing diabetes			
Understand diabetes and treatment	5.07(1.17)	5.08(1.46)	4.79(1.43)
Able to fit diabetes into your life	5.35(1.44)	5.45(1.63)	5.24(1.45)
Walking amount	2.24(1.35)	2.46(1.41)	2.53(1.23)
Comfort asking questions	6.27(1.21)	6.24(1.31)	6.09(1.34)
Laboratory tests			
A1C, % ↓	7.11(1.11)	7.13(1.42)	7.28(1.25)
Blood pressure	1.72(.22)	1.75(.25)	1.73(.28)
HDL-C, mmol/L ↑	1.28(.39)	1.20(.29)	1.24(.36)
LDL-C, mmol/L ↓	2.50(.90)	2.43(.70)	2.49(.91)
Weight kg. ↓	89.6(22.6)	86.7(19.1)	88.1(22.9)
Body mass index	30.8(6.4)	30.4(6.1)	30.3(6.7)
Waist circumference	106.9(16.6)	102.3(15.5)	104.6(19.4)

A1C = glycated hemoglobin
HDL-C = high-density lipoprotein cholesterol
LDL-C = low-density lipoprotein cholesterol
Numbers in parentheses give range of the scales. Arrows (↑↓) indicate direction of improvement

Statistical tests found that there were no differences between outcome measures in the three groups.

Description of Analysis

To assess the effectiveness of the program, the data was analyzed in two ways. In the first set of analyses, all patients in the program, whether they were in the DSMP or the CDSMP group, were combined and compared to those in the control group. In the second set of analyses, the two intervention groups and the control group were compared, as we also wanted to see if the DSMP and CDSMP programs resulted in different impacts on the patients.

For both sets of analyses, two-way factorial analyses of variance (ANOVAs, conducted as general linear models (GLMs) using STATA version 11.0), with one between-subjects and one repeated measures factors, were employed as the primary statistical analyses. The between-subjects factor was groups, using either 2 groups (control group and the combined DSMP and CDSMP group) or the 3 groups separately. The repeated measures factor was time, with the three time points of measurement (at baseline, 6 months, and 12 months) on each of the dependent measures (e.g., self-rated health, health distress, fatigue, etc.; for the full list see Table 2). The dependent measures were analyzed individually (i.e., not as a multivariate ANOVA) because they are unrelated to each other, and we were interested to see whether or not participation in a self-management program impacted each one separately. A significance level of 0.05 was set for statistical hypothesis testing for each ANOVA.[1] Significant effects were explored using post-hoc tests on the simple main effects that compare each treatment group mean to the control group mean at each time point. For significant effects, we also report the estimated effect size, as given by partial eta-squared; this gives the proportion of the total variability in the outcome measure that is explained by the joint effect of the group and time factors (and removing the individual effects of each factor alone).

In each ANOVA, it is the interaction effect between the group and time factors that is of interest. At baseline, prior to any treatment, the means of all outcome measures should be the same across all groups because of random assignment to the groups and the one-way ANOVAs confirmed that the three groups of patients did not differ statistically on any of the 30 outcome measures (all p-values were >.09) at baseline. Then, if the program had had an effect on the participants, the group means would differ at the later time points of measurement, and this would be indicated by a significant group by time interaction effect within the ANOVA. Dependent measures showing significant interactions were plotted, and post-hoc tests were conducted to determine which groups differed.

[1] The .05 level is a relatively liberal criterion, and raises the probability of making a Type I error within the experiment, as there are 30 measures that are being statistically tested in each set of analyses. To keep the experiment-wise Type I error rate at the .10 level for all 30 measures in the experiment, each measure could be tested at the .003 level of significance (i.e., using the Bonferroni correction .10/30 tests = .0033). This lowering of the per-ANOVA significance level and the probability of making a Type I error of incorrectly rejecting a null hypothesis, however, increases the probability of a Type II error and potentially missing some interesting findings. Because this is a relatively small study (with small Ns) and may lack statistical power to detect smaller yet interesting and meaningful treatment effects, we have kept the per-ANOVA significance level at .05, and report the individual p-values.

Results

A) Control vs. Self-Management Participants (2 Group Analyses)

The statistical significance of the group by time interactions, summarized in Table 3, show that the self-management program had affected five of the 30 measures (at the .05 or higher level of significance): Fatigue, cognitive symptom management, self-efficacy with regard to the disease in general, communication with physician, and the score on the DES. In addition, three variables – social role limitations, total hospital nights, and A1C – showed marginally significant interaction effects with p-values less than .10.

Table 3. Group (2 groups – DSMP & CDSMP combined vs. Control group – by Time effects)

Outcome measure	Mean Square Error (MSE)	F-value[(1)]	p-value	Effect Size (partial eta^2)
Self-rated Health	0.203	<1.00	>.50	
Health Distress	0.392	1.49	.23	
Social Role Limitations	*0.295*	*2.40*	*.092*	
Fatigue	***1.815***	***4.01***	***.019****	***.0167***
Shortness of Breath	1.697	1.87	.16	
Pain	2.629	<1.0	>.50	
Diabetes Empowerment	***0.120***	***17.59***	***<.001****	***.0712***
Illness Intrusiveness	50.139	<1.0	>.50	
PHQ-9 Depression Score	7.695	1.27	.28	
Depressive Symptoms	9.878	<1.0	>.50	
Communication with Physician	***0.435***	***4.73***	***.009****	***.0197***
Cognitive Symptom Mgmt	***0.292***	***3.38***	***.035****	***.0151***
Self-efficacy to Mx Symptoms	1.887	<1.0	>.50	
Self-efficacy to Mx Disease	***1.681***	***3.57***	***.029****	***.0151***
Number of physician visits	6.412	<1.0	>.50	
Number of times hospitalized	0.123	<1.0	>.50	
Total Hospital Nights	*3.292*	*2.85*	*.059*	
Understanding diabetes and Tx	0.640	1.54	.22	
Able to fit diabetes into life	0.814	<1.0	>.50	
Walking amount	0.769	<1.0	>.50	
Comfort asking questions	0.590	<1.0	>.50	
Hemoglobin A1C	*0.356*	*2.49*	*.085*	
Blood Pressure	0.030	<1.0	>.50	
HDL Cholesterol	0.175	<1.0	>.50	
LDL Cholesterol	0.242	<1.0	>.50	
Weight (kg)	16.461	<1.0	>.50	
Body Mass Index	3.872	<1.0	>.50	
Waist Circumference	19.223	1.76	.17	

Notes: * p<.05; ** p<.001

(1) The degrees of freedom for the F-statistic were 2 for the numerator and ranged between 314 and 472 for the denominator.

To examine the five outcome measures where the interaction was statistically significant (plus A1C which was marginally significant and an important measure), the group means are plotted in Figure 2. Post-hoc analyses (of simple main effects between groups at each time point) indicated that the statistically significant different occurrence primarily at 12 months.

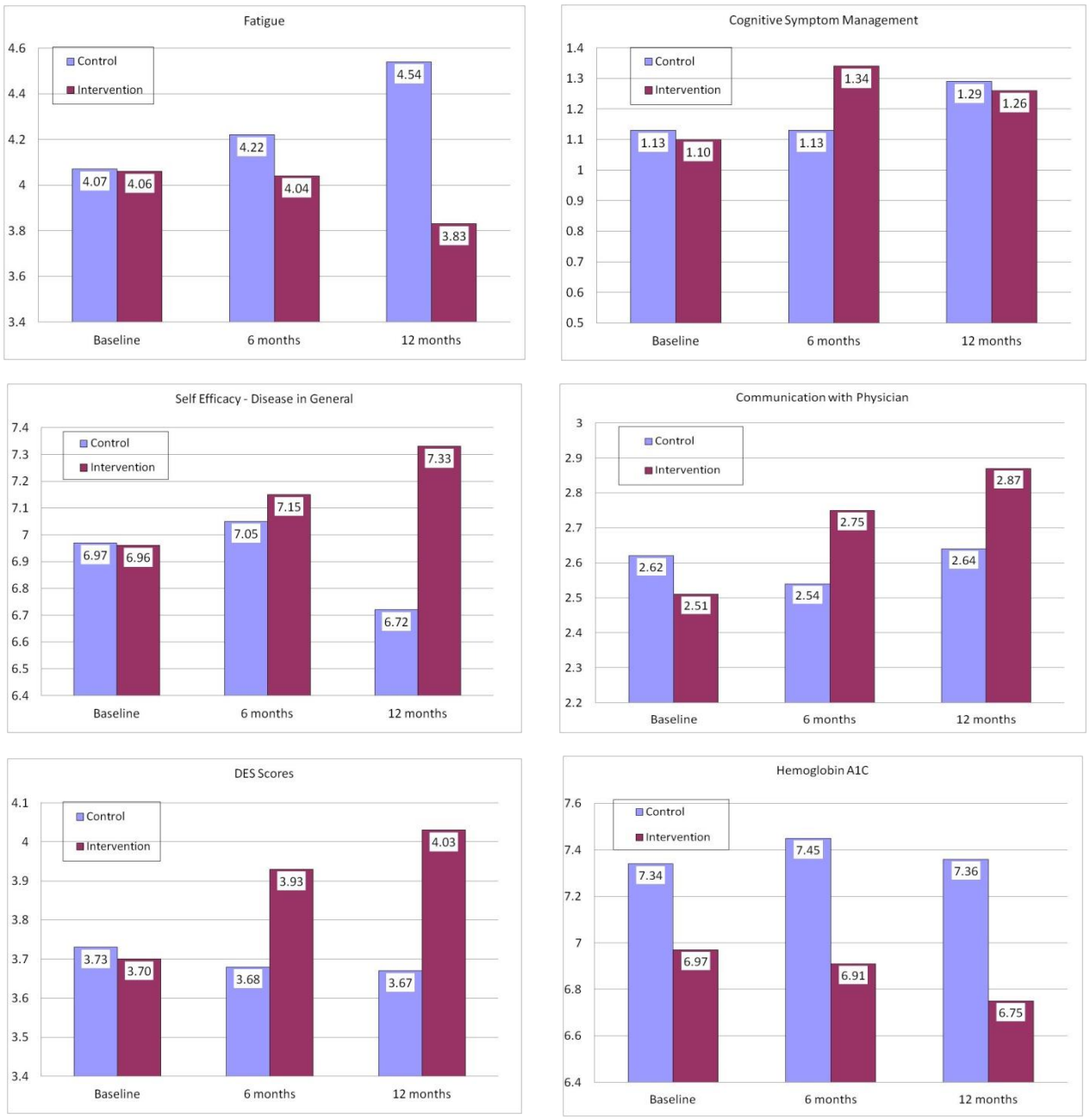

Figure 2. Effect of the Patient Self-Management Program on (a) Fatigue, (b) Cognitive Symptom Management; (c) Self-efficacy - Disease in General, (d) Communication with Physician, (e) DES Scores, and (f) Hemoglobin A1C.

In addition to the statistically significant interactions noted above, there were also some main effects of both group and time. When averaged over all three time points, the two groups differed on: health distress (experimental group M = 1.55, control group M = 1.86), illness intrusiveness (experimental group mean = 32.86, control group mean = 37.19), DES (experimental group M = 3.88, control group M = 3.69), A1C (experimental group M = 6.88, control group M = 7.38), and marginally (with $p<.10$) for pain (experimental group M = 2.98, control group M = 3.49), understanding diabetes and treatment (experimental group M = 5.43, control group M = 5.14) and PHQ-9 (experimental group M = 5.21, control group M = 6.41).

For those measures that did not show a statistically significant time by group interaction, the self-management programs also impacted the two groups differently overall. That is, when the participants' scores were averaged over time (i.e., ignoring the time factor), the treatment groups scored overall lower than the control group on measures of health distress, illness intrusiveness, A1C, and to some degree on pain, understanding diabetes and treatment, and the PHQ-9. Because the interaction over time did not reach statistical significance, this means that the two groups differed by about the same amount at each time point (within the variability of the scores at the three time points).

With measures that did have a significant interaction, interpreting the overall group means, from the significant main effects, does not shed additional light on how the program impacted the measures because the interpretation of the interaction provides the full picture.

All patients, regardless of group membership, also changed over time on: cognitive symptoms (means increased from T1 (M = 1.11) to T2 (M = 1.26) and T3 (M = 1.27)), depressive symptoms (T1 M = 8.87 and dropped to M = 8.29 at T2 and M = 8.261 at T3), communication with physician (M = 2.55 at T1 and increased to 2.67 at T1 and 2.78 at T3), understanding of diabetes and treatment (M = 4.97 at T1 and increased to M = 5.55 at T1 and 5.48 at T3), ability to fit diabetes into life (M = 5.36 at T1 and increased to M = 5.55 at T2 and 5.65 at T3); DES (M = 3.71 at T1 and increased to M = 3.84 at T2 and 3.89 at T3), BMI (M = 30.22 at T1 and 30.22 at T2 and decreased to 29.65 at T3); and weight (in kg) (M = 86.17 at T1 decreasing over time to 85.75 at T2 and 84.75 at T3), marginally (with $p<.10$) on walking amount (decrease at T3, compared with T1 and T2), A1C (M = 7.09 at T1 and 7.09 at T2, and decreased to M = 6.95 at T3), LDL (M = 2.42 at T1 and 2.40 at T2 and decreased to 2.29 at T3) and waist circumference (M = 103.2 cm at T1 and decreasing to 102.9 at T2 and 101.9 at T3).

We also found some overall effect of time, whereby all patients regardless of group membership improved (e.g., some improvement on depressive symptoms, ability to fit diabetes into life). This simply indicates that over the course of a year, everyone on average experienced similar life changes not due to the self-management programs per se.

B) Control vs. DSMP vs. CDSMP (3 Group Analyses)

Looking at the effects of the two programs separately, and compared with the control group the interactions for each outcome measure are summarized in Table 4. The results are quite similar, with four of the five measures remaining statistically significant – fatigue, cognitive symptom management, communication with physician, and diabetes empowerment.

Table 4. Group (3 groups) by Time effects on the outcome measures

Outcome measure	Mean Square Error (MSE)	F-value *	p-value	Effect Size (partial eta^2)
Self-rated Health	0.203	<1.00	>.50	
Health Distress	0.391	1.46	.21	
Fatigue	***1.811***	***2.73***	***.029****	***.0227***
Shortness of Breath	1.695	1.53	.19	
Pain	2.636	<1.0	>.50	
Walking Amount	0.771	<1.0	>.50	
Cognitive Symptom Management	***0.288***	***3.44***	***0.009****	***.0305***
Illness Intrusiveness	50.346	<1.0	>.50	
Self-efficacy to Mx symptoms	1.892	<1.0	>.50	
Self-efficacy - disease general	1.688	1.79	.13	
Depressive Symptoms	9.915	<1.0	>.50	
Social Role Limitations	0.296	1.21	.31	
Communication w/ physician	***0.436***	***2.39***	***.050****	***.0200***
Number of Physician Visits	6.428	<1.0	>.50	
Number of times hospitalized	0.123	1.33	.26	
Total Hospital Nights	3.288	1.64	.16	
Understanding Diabetes and Tx	0.642	1.11	.35	
Able to fit diabetes into life	0.818	<1.0	>.50	
Comfort asking questions	0.588	1.31	.27	
Diabetes Empowerment Scale	***0.120***	***9.14***	***<.0001****	***.0741***
PHQ-9 Score	7.713	<1.0	.49	
Hemoglobin A1C	0.358	1.33	.26	
Blood Pressure	0.030	1.18	.32	
HDL Cholesterol	0.173	<1.0	>.50	
LDL Cholesterol	0.242	1.41	.23	
BMI	3.871	<1.0	>.50	
Weight (kg)	16.428	<1.0	.46	
Waist circumference	19.307	1.04	.39	

Notes: * p<.05; ** p<.001
The degrees of freedom for the F-statistic were 4 for the numerator and 470 for the denominator.

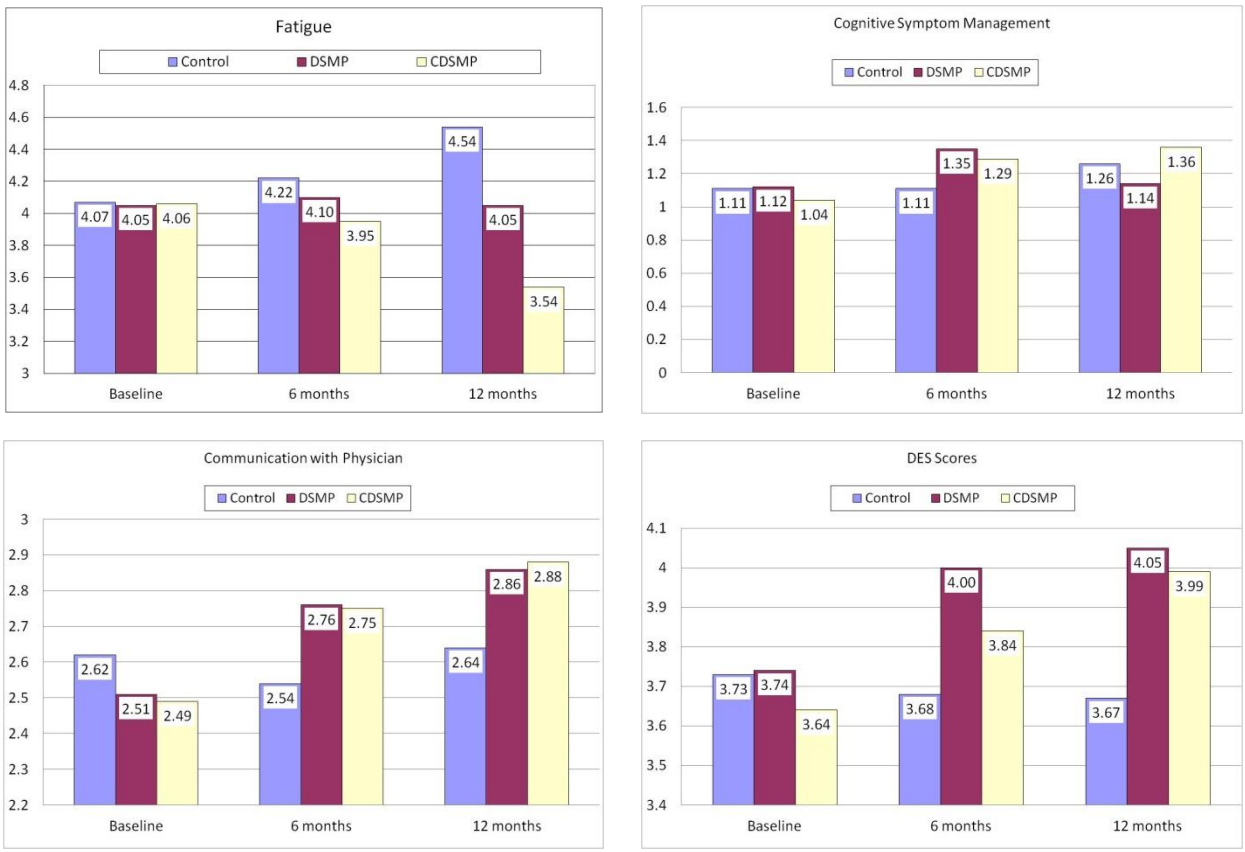

Figure 3. Effect of the Patient Self-Management Program on (a) Fatigue, (b) Cognitive Symptom Management, (c) Communication with Physician, and (d) DES Scores.

Main effects of group. Two dependent measures differed significantly across groups: DES (p=.022; Means were 3.93 for DSMP, 3.83 for CDSMP, and 3.69 for control) and A1C (p=.015; Means were 6.91 for DSMP, 7.00 for CDSMP, and 7.32 for control). In other words, when averaged across time, patients in the two self-management programs had higher means on the DES scale and lowered A1C levels than patients in the control group.

Main effects of time. As expected from the two group analyses, the same dependent measures changed significantly across time, when all participants (across all groups) were combined, namely: walking (p=.039), cognitive symptom management (p=.001), communication with physician (p<.001), understanding diabetes and treatment (p<.001), able to fit diabetes into life (p=.006), DES (p<.001), A1C (p=.015), BMI (p=.001) and weight (p<.001).

Discussion

With respect to the two-group analysis, participation in the self-management programs led to significant improvements in patients on five measures and marginally on A1C. With fatigue, while the control group increased in their fatigue over the 12 months, patients in the self-management programs decreased their fatigue (mostly between 6 and 12 months). For self-efficacy, communication with physician, diabetes empowerment, and A1C, the control group remained at the same level for the 12-month period while those in the self-management groups experienced improvements. Finally, for cognitive symptom management, at 6 months those in the self-management programs showed an improvement but by 12 months the control group also showed the same level of improvement. Furthermore, participants in the self-management programs showed an improvement in overall scores on health distress and illness intrusiveness. The three group analysis showed that there were significant differences between the intervention groups only for fatigue and diabetes empowerment.

Qualitative Research - Focus Group Meetings

Subjects who participated in one of the self-management programs were invited to attend a focus group meeting to share their experiences. Two meetings were conducted involving 30 persons.

Nearly all participants described ongoing difficulty and frustration with eating and diet. Mostly everyone was aware of how they should be eating but reported low self-control and difficulty avoiding high calorie foods particularly in social situations, eating on time, and not eating enough to maintain their blood glucose. Several reported feeling guilty about having excess weight and helpless because they had not been successful in losing this extra weight.

People said they felt embarrassed to tell others they had diabetes and they had trouble in accepting the diagnosis especially when they compared themselves to others with diabetes. They resented having diabetes because it put limitations on daily activity and forced them to decrease social activities. Some felt isolated and wanted to be connected with others for support but had no one to talk to. Several people volunteered they felt depressed and were afraid of what the future might look like. Others said they felt frustrated because diabetes seemed to affect people differently. They wanted to understand diabetes and to know how much was in their control as they kept gaining weight and A1C levels kept rising. Helplessness was a common theme and one of the main reasons they signed up for the study.

Other problems living with diabetes included a feeling of “aging faster”, specifically: being always fatigued, worn out, beat, and exhausted; having periodic pains; problems with memory, concentration and focus; trouble sleeping and waking up during the night and having to go to the bathroom at night; dropping things; and having thin skin that cuts easily and the length of time it takes for cuts to heal. Focus group participants generally agreed that they had good working

relationships with their family doctors but reported that they were experiencing problems with their medications. This included remembering to take the medication, not knowing if they were taking it in the right manner (i.e., with or without food) and covering the expense of the medication.

Focus group members said they had signed up for the study to gain more knowledge about diabetes, to hear about what new treatments were available, to find the motivation they were lacking and to learn more about self-management to avoid pills. The participants liked the group interaction hearing what others were doing and how it was working; they praised the quality of the peer leaders and the connection they had with the leaders and other class participants was excellent. The leaders touched base one-to-one, checked in at the breaks with all participants who also commented on the buddy system for helping one another and the feeling of being able to help another person. The checking on each person's progress was appreciated as it made them feel part of the group and that no one was on their own. Other feedback included the enjoyment of a relaxed atmosphere because the leaders were lay persons just like them and that the leaders were especially helpful when group members were unable to complete their action plans and this encouragement was also provided by other group members. The workshop sections on food and healthy diet and reading and interpreting food labels was well received and participants commented that this was exactly what they needed as it was like a refresher combined with learning the problem-solving process and how the symptom cycle works as being really helpful. Focus group members believed that that the main things they got out of the program were that they again realized: they were responsible for their health, the importance of healthy diet and proper eating habits, the need for more exercise and to exercise properly, to focus on moving forward in a healthy way and to keep up to date and knowledgeable on diabetes.

Participants felt that the self-management programs needed to be accessible to accommodate working persons and to hold evening classes for younger people. Also, they felt that 6 weeks is a large commitment for career/working people and the sessions could be reduced to 2 hours. They indicated it was beneficial to have a standard protocol across health regions for diabetes education and there was a need to advertise more, especially to doctors' offices because people didn't know about the self-management programs. Participants felt that a protocol is needed to refer persons to self-management program as soon as they are diagnosed, even with pre-diabetes.

Focus group participants provided two insightful suggestions regarding 6-week self-management programs, namely: 1) that a reinforcement session was needed approximately 6 months after program completion; and 2) to add an additional session to the program, for a diabetes clinician to describe current and new treatments and to address clinical questions.

Implications

The first major finding is that this study, which used a randomized controlled trial, found that the self-management program had positively affected five of the 30 outcome measures (at the .05 or higher level of significance), namely: fatigue, cognitive symptom management, self-efficacy with regard to the disease in general, communication with physician and diabetes empowerment. In addition, three variables – social role limitations, total hospital nights, and A1C – showed marginally significant interaction effects with p-values less than .10. This information will augment the international body of knowledge on effectiveness of self-management programs with type 2 diabetes.

The second major finding is that while both programs were effective in bringing about positive changes on the outcome measures, there was little difference in effectiveness between the DSMP program and the CDSMP program. This finding is consistent with the principle that behaviour change strategies using self-efficacy are key components in health education programs.

Dissemination

A summary of the findings has been sent to the 238 study participants (Appendix C). A summary has also been sent to each of the physicians who had their patient(s) enrolled (Appendix D).

The results of this study have been presented at the 9th Lawson Diabetes Workshop in Montreal on October 16, 2013 and at the International Diabetes Federation Conference in Melbourne Australia in December 2013. In addition, abstracts have been submitted to the Canadian Association on Gerontology meeting in Niagara Falls in October, 2014 as well as the Canadian Diabetes Association and Canadian Society of Endocrinology and Metabolism 17th Annual Professional Conference and Annual Meeting taking place in October, 2014.

This report will be disseminated through the international self-management community and will be available on the University of Victoria Self-Management BC website www.selfmanagementbc.ca. As well, it will be distributed to the organizations providing self-management programs across Canada. Importantly, this report is being submitted for publication in the Canadian Journal of Diabetes and an informational article is being submitted to the CDA Diabetes Communicator.

References

1. National Council on Aging. Using the evidence base to promote healthy aging. Published Spring 2006. Accessed April 27, 2014. http://www.ncoa.org/news-ncoa-publications/publications/issuebrief_1-r_usingeb.pdf
2. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: A randomized trial. *Med Care* 1999; 37(1):5-14.
3. Sobel DS, Lorig KR, Hobbs M. Chronic condition self-management program: From development to dissemination**.** *Perm J* 2002; 6(2):11-8.
4. Lorig K, Ritter P, Stewart A, et al. 2-year evidence that chronic disease self-management education has sustained health and utilization benefits. *Med Care* 2001; 39(11):1217-1223.
5. Kennedy A, Reeves D, Bower P, et al. The effectiveness and cost effectiveness of a national lay-led self-care support programme for patients with long-term conditions: A pragmatic randomised controlled trial**.** *J Epidem Com Health* 2007; 61(3), 254-61.
6. Swerissen H, Belfrage J, Weeks A, et al. A randomised controlled trial of a self-management program for people with a chronic illness from Vietnamese, Chinese, Italian and Greek backgrounds. *Patient Educ Couns* 2006; 64:360-368.
7. McGowan P, Green LW. Arthritis self-management in native populations in BC: An application of health promotion and participatory research principles in chronic disease control. *Can J Aging* 1995; 14(1):201-212.
8. Fu D, Fu H, McGowan P, et al. Implementation and quantitative evaluation of chronic disease self-management programme in Shanghai, China: Randomized controlled trial**.** *Bull World Health Org* 2003; 81(3):174-182.
9. Griffiths C, Motlib J, Azad A, et al. Randomised controlled trial of a lay-led self-management programme for Bangladeshi patients with chronic disease. *Br J Gen Pract* 2005; 55(520):831-837.
10. Fu D, Ding Y, McGowan P, Fu H. Qualitative evaluation of Chronic Disease Self-Management Program (CDSMP) in Shanghai**.** *Patient Educ Couns* 2006; 61(3), 389-96.
11. Nolte S, Osborne RH. A systematic review of outcomes of CDSM interventions. *Qual Life Res* 2013;22(7):1805-1816.
12. Brady TJ, Murphy L, Beauchesne D, et al. Sorting through the evidence for the Arthritis Self-Management program and the Chronic Disease Self-Management program, executive summary of ASMP/CDSMP meta-analyses. Centers for Disease Control and Prevention; May 2011.
13. Lorig KR, Ritter PL, Villa F, Piette JD. Spanish diabetes self-management with and without automated telephone reinforcement. *Diabetes Care* 2008:31(3):408-14.
14. Lorig K, Ritter PL, Villa FJ, Armas J. Community-based peer-led diabetes self-management: A randomized trial**.** *Diab Educ* 2009 July-August; 35(4):641-651.
15. Stewart AL, Ware JE, eds. *Measuring Functioning and Well-Being: The Medical Outcomes Study Approach.* Durham, NC: Duke University Press; 1992.
16. Kroenke K., Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med* 2001; 16:606-613.
17. Lorig K, Stewart A, Ritter P, et al. *Outcome Measures for Health Education and Other Health Care Interventions.* Thousand Oaks, CA. Sage Publications; 1996.
18. Devins GM, Binik YM, Hutchinson TA, Hollomby DJ, Barre PE, Guttmann RD. The emotional impact of end-stage renal disease: Importance of patients' perceptions of intrusiveness and control. *Int J Psychiatry Med* 1983; 13(4):327-343.
19. Anderson RM, Funnell MM, Fitzgerald JT, et al. The Diabetes Empowerment Scale: A measure of psychosocial self-efficacy. *Diabetes Care* 2000; 23:739-743.