Implementation and quantitative evaluation of chronic disease self-management programme in Shanghai, China: randomized controlled trial

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Objective To evaluate the effectiveness of the Shanghai Chronic Disease Self-Management Program (CDSMP).

Methods A randomized controlled trial with six-month follow-up compared patients who received treatment with those who did not receive treatment (waiting-list controls) in five urban communities in Shanghai, China. Participants in the treatment group received education from a lay-led CDSMP course and one copy of a help book immediately; those in the control group received the same education and book six months later.

Findings In total, 954 volunteer patients with a medical record that confirmed a diagnosis of hypertension, heart disease, chronic lung disease, arthritis, stroke, or diabetes who lived in communities were assigned randomly to treatment ($n = 526$) and control ($n = 428$) groups. Overall, 430 (81.7%) and 349 (81.5%) patients in the treatment and control groups completed the six-month study. Patients who received treatment had significant improvements in weekly minutes of aerobic exercise, practice of cognitive symptom management, self-efficacy to manage own symptoms, and self-efficacy to manage own disease in general compared with controls. They also had significant improvements in eight indices of health status and, on average, fewer hospitalizations.

Conclusion When implemented in Shanghai, the CDSMP was acceptable culturally to Chinese patients. The programme improved participants' health behaviour, self-efficacy, and health status and reduced the number of hospitalizations six months after the course. The locally based delivery model was integrated into the routine of community government organizations and community health services. Chinese lay leaders taught the CDSMP courses as successfully as professionals.

Keywords Chronic disease/therapy; Self care; Community health services; Hypertension/therapy; Coronary disease/therapy; Heart failure, Congestive/therapy; Lung diseases, Obstructive/therapy; Arthritis/therapy; Cerebrovascular accident/therapy; Diabetes mellitus/therapy; Cultural characteristics; Outcome assessment (Health care); Program evaluation; Randomized controlled trials; China (*source: MeSH, NLM*).

Mots clés Maladie chronique/thérapeutique; Auto-traitement; Service public santé; Hypertension artérielle/thérapeutique; Vaisseaux coronaires, Maladies/thérapeutique; Insuffisance cardiaque/thérapeutique; Bronchopneumopathies obstructives/thérapeutique; Arthrite/thérapeutique; Accident vasculaire cérébral/thérapeutique; Diabète/thérapeutique; Moeurs; Evaluation résultats (Santé); Evaluation programme; Essai clinique randomisé; Chine (*source: MeSH, INSERM*).

Palabras clave Enfermedad crónica/terapia; Autocuidado; Servicios de salud comunitaria/Hipertensión/terapia; Coronariopatía/terapia; Insuficiencia cardíaca congestiva/terapia; Neumopatías obstructivas/terapia; Artritis/terapia; Accidente cerebrovascular/terapia; Diabetes mellitus/terapia; Características culturales; Evaluación de resultado (Atención de salud); Evaluación de programas; Ensayos controlados aleatorios; China (*fuente: DeCS, BIREME*).

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Introduction

Chronic diseases — mainly heart disease, stroke, cancer, and lung disease — are becoming leading causes of disability and premature death in China. Noncommunicable diseases accounted for 81% of total deaths in China in 1996 (*1*). Chronic disease is also a major health care cost for China. In 1994, direct treatment costs related to chronic disease were more than four hundred billion Yuan (*2*). In China, Shanghai has the heaviest burden of noncommunicable diseases, because it has the largest population and the largest ageing population. Prevention and management of chronic disease is an urgent primary health problem to be addressed in Shanghai. The inability of current major health care systems to deal with chronic conditions calls for prompt policy action and new approaches to people with chronic conditions. Self-management for people with chronic disease is now widely recognized as a necessary part of treatment.

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Chronic disease self-management has been shown in the United States, Canada, and the United Kingdom to be useful in maintaining and improving patients' health behaviour and health status, while lowering health care utilization through improved self-management skills, "self-efficacy", and better communication between patients and health providers (*3–6*). The community-based generic self-management programme developed by Lorig et al. at Stanford University Patient Education Research Center — the Chronic Disease Self-Management Program (CDSMP) — is the most widely accepted self-management patient education programme worldwide, because it is designed to meet the needs of patients who have more than one chronic condition and is taught by trained lay leaders (*3*). The CDSMP is a community-based patient self-management education course. Several assumptions make this programme suitable for different kinds of patients (*7*): (1) people with chronic diseases have similar concerns and problems; (2) people with chronic conditions can learn to take responsibility for the day-to-day management of their disease(s) and the physical and emotional problems caused by their disease(s); (3) lay people with chronic conditions, when given a detailed leader's manual, can teach the CDSMP as effectively, if not more effectively, than health professionals; and (4) the process or way the CDSMP is taught is as important, if not more important, than the subject matter taught. The content and process of teaching the CDSMP course are based on self-efficacy theory (*8, 9*). Self-efficacy refers to people's beliefs in their abilities to perform specific behaviours, which is a key factor to behaviour change and health functioning (*9*). The courses incorporate strategies suggested by Bandura to enhance self-efficacy (*10*), including weekly action planning and feedback, modelling of behaviours and problem-solving by participants for one another, reinterpretation of symptoms, several different management techniques, group problem-solving, and individual decision-making. The leaders of the courses act more as facilitators than lecturers. The process is documented in a detailed protocol — the *Chronic disease self-management leader's manual* (*11*). Topics covered include: exercise; use of cognitive symptom management techniques; nutrition; fatigue and sleep management; use of community resources; use of medications; dealing with the emotions of fear, anger, and depression; communication with others, including health professionals; problem-solving; and decision-making. The content of the course was published as *Living a healthy life with chronic conditions* (*12*), which was used as a textbook for course participants.

To date, no research has tested whether CDSMP would be culturally acceptable for Chinese people and could benefit participants in China, or whether Chinese lay people could be trained to teach CDSMP courses as capably as professionals. This study examined the course's feasibility, benefits, and cultural sensitivity in Shanghai.

The study aimed to develop a Chinese culturally acceptable CDSMP, develop locally based sustainable CDSMP delivery models, and evaluate the effectiveness (changes in self-management behaviours, self-efficacy, health status, and health service utilization) of CDSMP for patients with at least one chronic condition through a randomized controlled trial in Shanghai. It also aimed to investigate whether trained lay leaders could teach CDSMP courses in China as effectively as professionals.

Methods

Patients

Eligibility criteria were men and women aged $\geqslant$20 years, at least one of hypertension, heart disease (coronary heart disease or congestive heart disease), chronic lung disease (asthma, chronic bronchitis, or emphysema), arthritis, stroke (completed cerebrovascular accident with neurological handicap and normal mentation), or diabetes confirmed by medical record, and community dwelling. Patients with other conditions as well as at least one of those described above were also included. Patients with compromised mentation, cancer patients who had received chemotherapy or radiation within the past year, patients for whom problems could be expected with compliance or follow-up, patients who had participated in another trial or study during the past 30 days, stroke patients with severe physical disability (that would interfere with them taking the CDSMP course), and patients aged <20 years were excluded. The community health centre and general practitioners were not informed of the participants' study status (treatment or control).

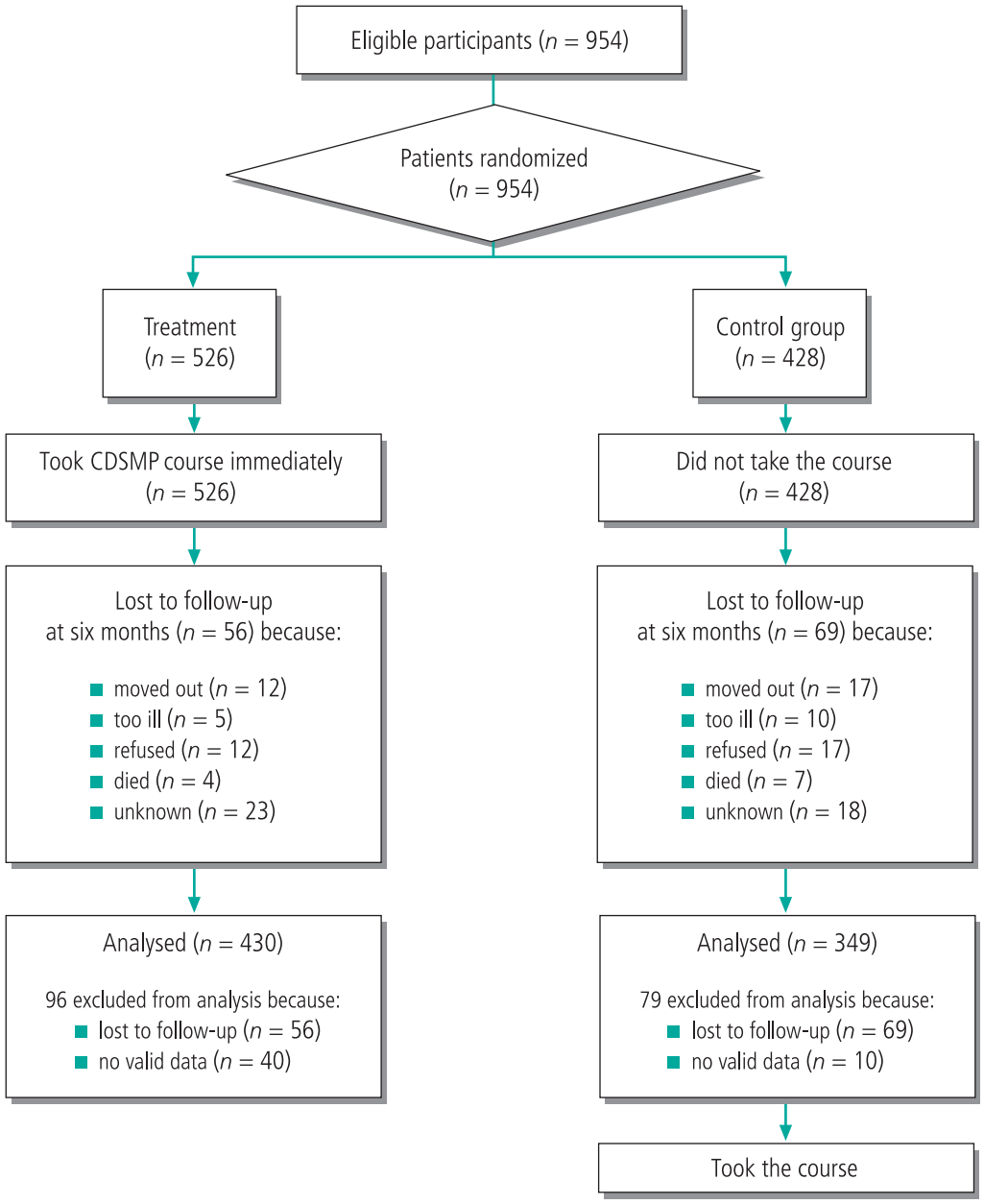
Recruitment and randomization

From June 1999 to February 2000, participants were recruited through public service announcements in the mass media, posters at community senior centres (activity centres for the community-dwelling elderly people), referrals from flyers left in community clinics, and interpersonal persuasion. The programme was run at multiple community sites in five communities in Shanghai, China, to ensure that it was easily accessible to patients. Randomization was conducted at each site. After the patient's eligibility and willingness to participate in the study were confirmed, each participant completed a baseline questionnaire. After informed consent was obtained, participants at each site were randomized into "treatment groups" (spring course) and "control groups" (autumn course), according to a random-number table with a randomization ratio designed to yield no fewer than ten and no more than 15 participants in a group. Neither the participants nor the data collectors were blind to the treatment assignment. As a result, 526 participants were placed in treatment groups and 428 in waiting-list control groups. Treatment group members received the CDSMP course immediately. Control group members received the CDSMP course six months after the treatment groups. Fig. 1 shows the trial profile.

Shanghai Chronic Disease Self-Management Program

The parts of *Chronic disease self-management leader's manual* and *Living a healthy life with chronic conditions* culturally unsuitable for the Chinese population were deleted or replaced. For example, because Chinese patients normally feel uncomfortable discussing issues of "death" and no "advance directives for health care" in China, the topic "making your wishes known: advance directives for health care" was deleted. We replaced some parts of "exercise for flexibility and strength" with physical activities that the Chinese people are familiar with and would feel comfortable doing, such as shadowboxing (Taiji) and eighteen exercises (a common Chinese exercise for improving joint flexibility and strength). In addition, we added some Chinese relaxation exercises and omitted some suggestions in "nearly 200 helpful hints", such as "going out by driving a new car",

Fig. 1. **Flow diagram of participants**



CDSMP = Shanghai Chronic Disease Self-Management Program.

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since such situations are not common in China. The materials then were translated and modified repeatedly after being pretested and reviewed by 20 patients with different common chronic diseases. The final Chinese versions of the two materials were written with common Chinese words and sentences. A community-based hypertension self-management group with ten volunteer patients with hypertension was established to pilot the content of the Shanghai CDSMP course and the process (the way in which the course was taught) (*13*). The experience and suggestions from the pilot study — for example that lay leaders should not be aged ⩾75 years — contributed to the later implementation of Shanghai CDSMP.

The Shanghai CDSMP included seven 2–2.5-hours sessions scheduled on consecutive weeks. The course was conducted in groups by two trained volunteer leaders who worked in pairs in community settings such as senior centres and community hospitals or in the patient's house; then followed the *Chronic disease self-management leader's manual*. One or both leaders were non-health professionals with a chronic disease themselves. Only 11 trained course leaders were health professionals in this study. Course participants took the CDMSP course and received a copy of the help book *Living a healthy life with chronic conditions* — the intervention group immediately and the control group six months later.

The implementation of CDSMP in Shanghai

According to participatory research principles (*14*), and considering the different local features of the five commu-

nities, the Shanghai CDSMP developed two delivery models. The first was the "commonly participatory model", in which the community government, community health centre, and researchers worked together to design, implement, and evaluate the programme by means of a community programme advisory committee. The CDSMP was integrated into the routine of community government organizations and community health services. In the second "professional dominated model", the community government organizations gave only passive support to the programme. The CDSMP was not integrated into their routines, but the community health centre contributed more to the programme than it did in the first model. Some community health care providers trained to be course leaders and taught part of the course; the researchers did the same. In terms of the process of CDSMP delivery, the scale and efficiency of community mobilization and programme advertisement in the commonly participatory model were higher than in the professional dominated model. Two communities used the first model and registered 588 course participants and 74 volunteer lay leaders. Three communities used the second model and registered only 366 participants and 57 volunteer lay leaders. The total population in each of the five communities was nearly 50 000. The five communities were all located at the centre of Shanghai city.

Sample size

Previous similar research showed that the effect size of CDSMP in six months is small (*3*). Given that 0.20 represents a small effect size, power computations with Power Chart software (*15*) for a balanced design indicated that 395 participants in each group would be sufficient to achieve 80% power with two-tailed tests and $\alpha = 0.05$. To assure 10–15 patients were included in the treatment group, the overall ratio of treatment-to-control patients was not 1:1. Based on 80% power to detect a significant difference ($P = 0.05$, two-sided), with an assumed overall ratio of 5:4 and a loss to follow up of 20%, 534 patients were needed in the treatment group and 428 in the control group.

Outcome measures and statistical analysis

Outcomes were measured with a pre-tested self-administered Chinese version of the questionnnaire on chronic disease self-management study measures developed by Lorig et al. (*7*). This includes four primary classifications of outcome variables (health behaviours, health status, self-efficacy, and health service utilization), which enable a description of how well people are managing their chronic disease. The four categories of 20 outcome variables are: (1) self-management behaviour change score (exercise, practice of cognitive symptom management, and communication with doctor); (2) self-efficacy score (self-efficacy to manage disease in general and self-efficacy to manage symptoms); (3) health status (self-rated health, health distress, shortness of breath, pain, disability, depression, energy and fatigue, and social and role activity limitations); and (4) health service utilization (visits to physicians, visits to emergency departments, number of hospital stays, and nights spent in hospital). The questionnaire was completed by participants at baseline and after six months. To minimize acquiescent response, data collection was separated completely from the intervention and was performed by people who did not know the patients or their treatment status.

The Mann-Whitney *U*-test was used to compare the baseline status of the treatment and control groups. Analysis of covariance was used to compare changes in the 20 outcome variables at six months between the treatment and control groups. The analysis controlled for the baseline value of the study variables that differed between the groups at baseline: age, sex, education, marital status, follow-up time, baseline number of minutes per week of stretching and strengthening exercise, cognitive symptom management practice, communication with medical doctor, and disability. The Mann-Whitney *U*-test also was used to detect differences in outcomes for those taught by professionals as opposed to those taught by lay leaders.

Results

Baseline characteristics

Of 954 subjects who entered the study, 486 patients in the treatment groups and 418 in the control group had valid baseline data. Only 430 (81.7%) patients in the treatment group and 349 (81.5%) in the control group completed the six-month study. A comparison of baseline data showed that 779 participants who completed the six-month study had significantly worse (higher scores for) shortness of breath and disability than those who did not complete ($P<0.05$). Table 1 gives the demographics and disease characteristics of the participants

Table 1. **Patient characteristics. Values are numbers (percentages) unless otherwise specified**

Characteristic	Treatment ($n = 430$)	Control ($n = 349$)
Mean ± SD[a] age (years)	64.21 ± 9.77	63.80 ± 10.30
Age range	29.2–89.8	22.1–88.9
Sex		
Female	315 (73.3)	241 (69.1)
Male	115 (26.7)	108 (30.9)
Ethnicity		
Han	413 (96.0)	342 (98.0)
Zhuang	9 (2.1)	5 (1.4)
Miao	5 (1.2)	1 (0.3)
Hui	3 (0.7)	1 (0.3)
Mean ± SD education (years)	9.48 ± 3.89	9.88 ± 3.88
Marital status		
Married	354 (82.3)	277 (79.4)
Separated	8 (1.9)	4 (1.1)
Widowed	60 (13.9)	60 (17.2)
Single	6 (1.4)	6 (1.7)
Divorced	2 (0.5)	2 (0.6)
Mean number ± SD of diseases	2.09 ± 1.22	1.95 ± 1.09
Disease prevalence		
Hypertension	223 (51.9)	208 (59.6)
Heart disease	146 (34.0)	117 (33.5)
Arthritis	137 (31.9)	101 (28.9)
Lung disease	90 (20.9)	61 (17.5)
Diabetes	75 (17.4)	46 (13.2)
Cancer	15 (3.5)	8 (2.3)
Other diseases	185 (3.0)	129 (40.0)
Mean ± SD follow-up time (months)	8.46 ± 0.59	8.30 ± 0.66[b]

[a] SD = standard deviation.
[b] $F = 12.86$, $P<0.001$.

who completed the study. Only follow-up time was significantly different between those in the treatment and control groups ($P<0.001$). Table 2 gives baseline data for the treatment and control groups. Controls spent significantly less time on stretching and strengthening exercises per week and they had fewer cognitive symptom management practices and fewer communications with doctors but had significantly better disability scores than patients in the treatment group.

Effectiveness of CDSMP intervention

Table 3 shows the mean change in scores at six months for the treatment and control patients. Compared with controls, patients in the treatment group had significant improvements in two of the four self-management behaviours. Treatment subjects, on average, increased their duration of aerobic exercise to >25 minutes per week ($P = 0.01$) and scores in practice of cognitive symptom management by 0.37 ($P = 0.005$). The treatment group had significant improvements in both measures of self-efficacy: increases of 0.69 and 0.63 in self-efficacy to manage symptoms and in self-efficacy to manage disease in general (both $P = 0.001$). Patients in the treatment group also had significant improvements in eight measures of health status (self-rated health, health distress, fatigue, shortness of breath, pain, disability, depression, and social and role activity limitations) ($P<0.05$). The treatment group had, on average, 0.12 fewer hospitalizations than the control group ($P = 0.04$).

It was necessary to control for the baseline value of the study variables age, sex, education, marital status, follow-up time, baseline number of minutes per week spent on stretching and strengthening exercises, cognitive symptom management practice, communication with medical doctor, and disability to compare the mean change in scores for the treatment and control patients at six months. Among the control variables, analysis of covariance on six month post-test scores showed that each baseline study variable significantly influenced some six-month changes: age significantly influenced changes in self-rated health, fatigue, and disability (younger people had better changes in six months); education significantly influenced changes in self-rated health, fatigue and self-efficacy to manage disease in general (patients with higher education levels had better improvements at six months); and disability significantly influenced changes in pain, shortness of breath, depression, and social and role activity limitation (patients with higher disability had worse improvements in those four variables in six months).

Table 2. **Baseline for treatment and control patients: self-management behaviour, health status, and health service utilization**

Variable	Mean ± SD		*P*-value[a]
	Treatment ($n = 430$)	Control ($n = 349$)	
Self-management behaviour			
Stretching and strengthening exercise (minutes/week)	20.26 ± 45.65 ($n = 422$)[b]	13.21 ± 39.81 ($n = 344$)	0.002
Aerobic exercise (minutes/week)	179.54 ± 130.50 ($n = 421$)	177.18 ± 133.05 ($n = 344$)	0.27
Cognitive symptom management[c]	1.19 ± 0.98 ($n = 407$)	0.79 ± 0.81 ($n = 340$)	0
Communication with medical doctor[c]	1.48 ± 0.97 ($n = 416$)	1.24 ± 1.07 ($n = 341$)	0
Self-efficacy[d]			
Managing symptoms	7.08 ± 2.22 ($n = 392$)	7.04 ± 2.22 ($n = 336$)	0.82
Managing disease in general	7.36 ± 2.12 ($n = 398$)	7.23 ± 2.21 ($n = 333$)	0.56
Health status			
Self-rated health[e]	3.93 ± 0.59	3.89 ± 0.60	0.30
Energy[c]	2.56 ± 0.89 ($n = 409$)	2.53 ± 0.81 ($n = 342$)	0.83
Health distress[f]	0.90 ± 0.91 ($n = 411$)	0.83 ± 0.86 ($n = 342$)	0.31
Fatigue[g]	3.53 ± 2.23 ($n = 424$)	3.29 ± 2.10 ($n = 346$)	0.12
Shortness of breath[g]	2.18 ± 1.87 ($n = 424$)	2.09 ± 1.73 ($n = 346$)	0.71
Pain[g]	2.36 ± 2.07 ($n = 424$)	2.27 ± 1.99 ($n = 346$)	0.60
Disability[k]	0.12 ± 0.28 ($n = 423$)	0.07 ± 0.22 ($n = 342$)	0.02
Illness intrusiveness[h]	25.48 ± 14.36 ($n = 415$)	25.96 ± 14.01 ($n = 335$)	0.54
Depression[i]	7.68 ± 4.25 ($n = 403$)	8.04 ± 4.19 ($n = 339$)	0.15
Social/role activity limitations[j]	0.75 ± 0.81 ($n = 415$)	0.70 ± 0.77 ($n = 340$)	0.36
Health care utilization (no. of times in previous six months)			
Physician visits	8.05 ± 8.98	7.61 ± 7.44	0.59
Emergency room visits	0.16 ± 0.84	0.13 ± 0.53	0.93
Hospital stays	0.13 ± 0.38	0.11 ± 0.32	0.53
Nights in hospital	1.57 ± 8.18	0.87 ± 3.99	0.58

[a] Mann-Whitney *U*-test was used to compare baseline variables between treatment and control groups (two-tailed *P*-values).
[b] Several variables had data missing, which is shown in the table.
[c] 0–5 increase = improvement.
[d] 1–10 increase = improvement.
[e] 1–5 decrease = improvement.
[f] 0–5 decrease = improvement.
[g] 0–10 decrease = improvement.
[h] 13–91 decrease = improvement.
[i] 0–30 decrease = improvement.
[j] 0–4 decrease = improvement.
[k] 0–3 decrease = improvement.

Table 3. **Six-month changes for treatment and control subjects: self-management behaviors, health status, and health service utilization**

Variable	Mean ± SD change		*P*-value[a]
	Treatment (*n* = 430)	Control (*n* = 349)	
Self-management behaviour			
Stretching and strengthening exercise (minutes/week)	3.54 ± 64.10 (*n* = 411)[b]	4.44 ± 55.13 (*n* = 321)	0.07
Aerobic exercise (minutes/week)	27.93 ± 175.51 (*n* = 406)	2.68 ± 136.51 (*n* = 319)	0.01
Cognitive symptom management[c]	0.37 ± 0.95 (*n* = 391)	0.04 ± 0.76 (*n* = 305)	0.005
Communication with medical doctor[c]	0.04 ± 1.24 (*n* = 396)	0.11 ± 1.32 (*n* = 308)	0.89
Self-efficacy in self-management[d]			
Managing symptoms	0.52 ± 2.11 (*n* = 378)	–0.17 ± 2.67 (*n* = 301)	0.001
Managing disease in general	0.22 ± 2.52 (*n* = 377)	–0.41 ± 2.87 (*n* = 297)	0.001
Health status			
Self-rated health[e]	–0.28 ± 0.79	–0.03 ± 0.72	0.001
Energy[c]	0.03 ± 1.03 (*n* = 380)	0.06 ± 1.01 (*n* = 294)	0.93
Health distress[f]	–0.24 ± 1.01 (*n* = 386)	–0.01 ± 1.12 (*n* = 296)	0.001
Fatigue[g]	–0.35 ± 2.70 (*n* = 411)	0.09 ± 2.52 (*n* = 326)	0.03
Shortness of breath[g]	0.05 ± 2.39 (*n* = 411)	0.38 ± 2.18 (*n* = 326)	0.01
Pain[g]	–0.04 ± 2.38 (*n* = 412)	0.34 ± 2.31 (*n* = 326)	0.02
Disability[k]	–0.07 ± 0.28 (*n* = 412)	0.01 ± 0.32 (*n* = 322)	0.005
Illness intrusiveness[h]	0.07 ± 17.01 (*n* = 403)	1.05 ± 17.71 (*n* = 305)	0.06
Depression[i]	–1.20 ± 5.23 (*n* = 385)	–0.66 ± 5.17 (*n* = 308)	0.004
Social/role activity limitations[j]	–0.09 ± 0.98 (*n* = 399)	0.06 ± 0.99 (*n* = 308)	0.046
Health care utilization (no. in previous six months)			
Physician visits	–1.01 ± 9.41	–0.84 ± 7.76	0.72
Emergency room visits	–0.04 ± 0.96	–0.03 ± 0.72	0.44
Hospital stays	–0.06 ± 0.46 (*n* = 430)	0.06 ± 0.92 (*n* = 348)	0.04
Nights in hospital	–0.55 ± 9.60	0.44 ± 6.72	0.40

[a] Analysis of covariance on six-month post-test scores controlling for the baseline value of study variables, age, sex, education, marital status, follow-up time, and baseline number of minutes per week of stretching and strengthening exercises, cognitive symptom management practice, communication with medical doctor, and disability (two-tailed *P*-values).
[b] Several variables had data missing, which is shown in the table.
[c] 0–5 increase = improvement.
[d] 1–10 increase = improvement.
[e] 1–5 decrease = improvement.
[f] 0–5 decrease = improvement.
[g] 0–10 decrease = improvement.
[h] 13–91 decrease = improvement.
[i] 0–30 decrease = improvement.
[j] 0–4 decrease = improvement.
[k] 0–3 decrease = improvement.

An intention-to-treat analysis was conducted with 893 subjects. Baseline data were used at six months for the 114 subjects lost to follow-up, although the four treatment and seven control patients who died were excluded. In this analysis, all probability values remained unchanged except for social and role activity limitations ($P = 0.06$), although the change scores were slightly lower for both treatment and control groups. For example, the change in aerobic exercise was 26.81 minutes per week for the treatment group compared with 2.30 minutes for the control group, changes in self-rated general health were –0.26 and –0.03 and fatigue were –0.32 and 0.07, and the numbers of hospital stays were –0.055 and 0.049.

Effect size of CDSMP intervention on significantly changed outcome variables

To evaluate treatment effectiveness, figures were prepared to show the effect on significantly changed outcome measures with a standardized statistic: the effect size. This allowed the comparison of effectiveness across measures with different scales and was calculated using the formulae below (*15*), in which μ_t = the mean change in outcome variables among members of the treatment group, μ_c = the mean change in outcome variables among members of the control group; σ = the common standard deviation (which can be estimated by S_p); S_p = the pooled standard deviation; s_t^2 and s_c^2 = the variances for the treatment and control groups, respectively; and n_t and n_c = the sample sizes for the treatment and control groups.

$$ES = \frac{\mu_t - \mu_c}{\sigma}$$

$$S_p = \sqrt{\frac{(n_t - 1)s_t^2 + (n_c - 1)s_c^2}{(n_t - 1) + (n_c - 1)}}$$

Table 4 shows that CDSMP had relatively large effects on cognitive symptom management, self-rated health, self-efficacy, and disability, but it had relatively small effects on depression.

Comparison of lay-taught and professional-taught CDSMP courses

The Mann-Whitney *U*-test was used to compare six-month changes of 20 outcome variables between 373 treatment

Table 4. **Effect size for chronic disease self-management programme in terms of significantly changed outcome variables**

Outcome variables	Effect size
Self-management behaviours	
Aerobic exercise (minutes/week)	0.16
Cognitive symptom management	0.38
Self-efficacy in self-management	
Managing symptoms	0.29
Managing disease in general	0.24
Health status	
Self-rated health	–0.33
Health distress	–0.22
Fatigue	–0.17
Shortness of breath	–0.14
Pain	–0.16
Disability	–0.27
Depression	–0.10
Social and role activity limitations	–0.15
Health service utilization (no. in past six months)	
Hospital stays	–0.17

subjects taught by lay leaders and 57 treatment subjects taught by professionals to determine whether outcomes were different. Only changes in self-rated health and fatigue differed significantly between the two groups. Patients in the lay-taught group had significantly better improvements in fatigue than those in the professional-taught group (–0.45 change in six months compared with 0.27; $Z = -2.01$; $P = 0.04$), but those in the professional-taught group had better self-rated health scores than those in the lay-taught group (–0.49 compared with –0.25; $Z = -2.18$; $P = 0.03$).

Preliminary analysis of Shanghai CDSMP cost versus saving

According to the decrease in number of hospitalizations in the six-month treatment period and the parameters shown in Table 5, a preliminary comparison of programme costs and savings was performed. This did not take into account indirect costs. The savings in health care expenditure approximated 726.79 Yuan per participant — nearly nine times the cost of the intervention.

Discussion

This study was an implementation and evaluation of a generic chronic disease self-management patient education programme for Chinese people with one or more chronic conditions in Shanghai. The content of the Shanghai CDSMP course was repeatedly modified, pre-tested, and piloted to guarantee that the course was culturally acceptable to course participants. The course was delivered to groups mainly by lay leaders who worked in pairs. This new health education format was liked by most participants, which made the implementation of CDSMP very successful, especially with the locally based delivery model — the commonly participatory model — in which the community government organizations, community health centre, and researchers worked together to design, implement, and evaluate the programme through a community programme advisory committee. Programme implementation

Table 5. **Parameters for cost benefit analysis of chronic disease self-management programme**

Parameter	Cost (Chinese Yuan)
Cost per participant[a]	
Programme advertisement	5.00
Training leaders	32.16
Volunteer leader stipends	20.00
Course materials	23.50
Administrative costs	2.00
Total	**82.66**
Cost per hospitalization[b]	**6745.45**

[a] Six training workshops were finished and 100 qualified volunteer leaders trained; assumes two leaders taught each course, that each leader taught only one course, and that ten participants formed one self-management group.
[b] Calculated from data from 330 participants' baseline surveys.

was integrated into the routine of community government organizations and community health services.

Overall, the Shanghai CDSMP was successful in increasing self-management behaviours, maintaining and improving health status, and decreasing health service utilization (Table 3). Chronic disease self-management approaches are widely accepted and are being disseminated (*16–21*). A five-year study by Lorig et al. showed that CDSMP can improve health behaviours (exercise, cognitive symptom management practice, and communication with physicians), health status (self-reported health, health distress, fatigue, disability, and social and role activity limitations), and decrease the number and duration of hospitalizations (*3*). This has prompted lay-led CDSMP courses to be disseminated internationally (*22–24*). No previous research has examined the feasibility and cultural appropriateness of CDSMP with Chinese people. This study showed that CDSMP can be accepted by Chinese people and can lead to benefits for the participants after it is modified carefully and delivered according to a locally based model. This has significant implications for noncommunicable disease prevention and control in China. Many patients with chronic conditions lack and need help with basic self-management knowledge and skills. At the same time, chronic disease is causing escalating health expenditure as the population in twenty-first century China rapidly ages.

Another interesting finding in the study was the comparison of the effectiveness between lay-taught and professional-taught groups. Professional-taught groups had better changes in self-rated health scores, but lay-taught groups had better changes in fatigue scores. Although it is impossible to draw definitive conclusions, this suggests that Chinese lay people could be trained to teach CDSMP courses as successfully as health professionals. The use of lay people as community health educators is very uncommon in China, so the result has strong implications for community health education practice in the future. In addition, the findings strengthen evidence from other studies that the use of lay instructors in community-based health promotion and chronic illness self-management programme is cost-effective (*25–27*).

One key question concerns the generalizability of the findings. As in all similar studies, participants in this study were volunteers who were recruited mainly through community mass media and interpersonal channels. The participants self-

selected to be in the study and may have been more motivated than most patients with chronic disease. Evidence shows that 47% of patients repeatedly offered an opportunity to participate in an education programme similar to CDSMP will choose to do so (*3, 28*). This suggests that research on dissemination of CDSMP in Shanghai in the future may need to look at the reasons why patients attend or refuse to attend courses and to explore effective interventions to motivate patients to attend.

The participants in this study had a high mean level of education: the mean duration of education was nine years. The feasibility and effectiveness of CDSMP when conducted with patients with lower education levels, especially in rural communities, need further study.

The interpretation of this study is limited by the fact that nearly 20% of participants did not complete the study and that data are missing on some outcome variables. The real sample size ($n = 779$) was used to calculate statistical power with two-tailed tests and $\alpha = 0.05$. We found that 779 participants gave 79% power — 1% less than the targeted statistical power (80%).

It is important to note that the participants, community health centres, and general practitioners did not know participants' study status. No link existed between the CDSMP and the patient's individual treatment plans. The CDSMP did not alter participants' treatment. The benefits achieved were additional to those achieved by usual care. Integration of CDSMP with usual care presumably would give participants more self-management support from health care providers and would further enhance the benefits of the programme.

Conclusions

The Chronic Disease Self-Management Program developed in Shanghai from the generic Chronic Disease Self-Management Program was designed specifically to meet the needs of patients with one or more different chronic conditions, including those with comorbid conditions. The results of this study show that, when adapted, CDSMP is culturally acceptable to Chinese people and that it is feasible in China when delivered according to a locally-based model and integrated into the routine of community government organizations and community health services. In Shanghai, CDSMP had benefits similar to those demonstrated in previous studies in improving self-management behaviours and in health status and decreasing hospitalization, with a potential for substantial savings in health care costs. Chinese lay leaders can teach CDSMP courses as effectively as health professionals. If our results are replicated in more studies in China, CDSMP should be recommended for integration into the usual care of patients with chronic disease. ■

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Conflicts of interest: none declared.

Résumé

Mise en œuvre et évaluation quantitative du programme d'auto-prise en charge des maladies chroniques à Shanghai (Chine) : essai contrôlé randomisé

Objectif Evaluer l'efficacité du programme d'auto-prise en charge des maladies chroniques (CDSMP) à Shanghai.

Méthodes Lors d'un essai contrôlé randomisé avec suivi de six mois, on a comparé les patients ayant reçu un traitement avec des témoins non traités (patients inscrits sur une liste d'attente) dans cinq communautés urbaines de Shanghai (Chine). Les participants du groupe traité ont immédiatement suivi un cours organisé par le CDSMP et dispensé par des non-professionnels de la santé et reçu une brochure d'appui ; les participants du groupe témoin ont reçu les mêmes prestations six mois plus tard.

Résultats Au total, 954 volontaires dont le dossier médical confirmait un diagnostic d'hypertension, de maladie cardiaque, d'affection pulmonaire chronique, d'arthrite, d'accident vasculaire cérébral ou de diabète et résidant dans la communauté ont été répartis par tirage au sort entre un groupe traité ($n = 526$) et un groupe témoin ($n = 428$). Sur ce total, 430 patients du groupe traité (81,7 %) et 349 patients du groupe témoin (81,5 %) ont participé à l'étude jusqu'à la fin, c'est-à-dire pendant six mois. Par rapport aux témoins, les patients traités ont présenté une amélioration significative en ce qui concerne la durée hebdomadaire (en minutes) d'exercice aérobie, la pratique de la prise en charge des symptômes cognitifs, l'auto-efficacité de la prise en charge de leurs symptômes et l'auto-efficacité de la prise en charge de leur maladie en général. Ils présentaient également une amélioration significative de huit indicateurs de l'état de santé et subissaient en moyenne moins d'hospitalisations.

Conclusion Mis en œuvre à Shangai, le CDSMP était culturellement acceptable pour les patients chinois. Six mois après le cours, le programme avait amélioré le comportement des participants en rapport avec la santé, leur auto-efficacité et leur état de santé et avait réduit le nombre d'hospitalisations. Le modèle appliqué, conçu au niveau de la communauté, était intégré dans les activités de routine des organismes publics communautaires et des services de santé de la communauté. Les Chinois non professionnels de la santé qui ont dispensé les cours du CDSMP l'ont fait aussi efficacement que des professionnels.

Resumen

Aplicación y evaluación cuantitativa del programa de automanejo de enfermedades crónicas en Shanghai (China): ensayo controlado aleatorizado

Objetivo Evaluar la eficacia del Programa de Automanejo de Enfermedades Crónicas de Shanghai (PAECS).

Métodos En un ensayo controlado aleatorizado con seguimiento de seis meses se procedió a comparar a los pacientes que recibieron tratamiento con los que no lo recibieron (controles de la lista de espera) en cinco comunidades urbanas de Shanghai (China). Los participantes en el grupo de tratamiento recibieron de inmediato formación mediante un cursillo de PAECS dirigido por un no profesional de la salud, así como un ejemplar de un libro de ayuda; los del grupo control recibieron la misma formación y el mismo libro seis meses después.

Resultados En total, 954 pacientes voluntarios con una historia clínica que confirmaba un diagnóstico de hipertensión, cardiopatía, enfermedad pulmonar crónica, artritis, ictus o diabetes y que vivían en comunidades fueron asignados aleatoriamente al grupo de tratamiento (n=526) o al grupo control (n=428). Globalmente, 430 (81,7%) y 349 (81,5%) pacientes de los grupos tratado y control, repectivamente, terminaron el estudio de seis meses. Los pacientes que recibieron tratamiento experimentaron mejoras significativas en lo que respecta al número de minutos semanales dedicados a ejercicios de aeróbic, los resultados de las pruebas cognitivas y la eficacia del automanejo de la propia enfermedad en general en comparación con los controles. Presentaron asimismo mejoras importantes en ocho indicadores del estado de salud y, como media, menos hospitalizaciones.

Conclusión Los pacientes chinos abarcados por el PAECS lo consideraron culturalmente aceptable. Al cabo de seis meses el programa había mejorado el comportamiento sanitario, la eficacia del control autónomo y el estado de salud de los participantes, y reducido el número de hospitalizaciones. El modelo asistencial local se integró en las actividades ordinarias de las organizaciones de gobierno de la comunidad y de los servicios de salud comunitarios. Los chinos no profesionales impartieron los cursillos del PAECS con la misma eficacia que los profesionales.

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