

## A Randomized Controlled Trial of Clinician-Supported Problem-Solving Bibliotherapy for Family Caregivers of People With First-Episode Psychosis

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**Family interventions for first-episode psychosis (FEP) are an integral component of treatment, with positive effects mainly on patients' mental state and relapse rate. However, comparatively little attention has been paid to the effects of family interventions on caregivers' stress coping and well-being, especially in non-Western countries. We aimed to test the effects of a 5-month clinician-supported problem-solving bibliotherapy (CSPSB) for Chinese family caregivers of people with FEP in improving family burden and carers' problem-solving and caregiving experience, and in reducing psychotic symptoms and duration of re-hospitalizations, compared with those only received usual outpatient family support (UOFS). A randomized controlled trial was conducted across 2 early psychosis clinics in Hong Kong, where there might be inadequate usual family support services for FEP patients. A total of 116 caregivers were randomly selected, and after baseline measurement, randomly assigned to the CSPSB or UOFS. They were also assessed at 1-week and 6- and 12-month post-intervention. Intention-to-treat analyses were applied and indicated that the CSPSB group reported significantly greater improvements in family burden and caregiving experience, and reductions in severity of psychotic symptoms and duration of re-hospitalizations, than the UOFS group at 6- and 12-month follow-up. CSPSB produces moderate long-term benefits to caregivers and FEP patients, and is a low-cost adjunct to UOFS.**

*Key words:* burden/experience of caregiving/family intervention/patients/relapse

### Introduction

The development of first-episode psychosis (FEP) in a family member can place substantial burden on family

caregivers and adversely affect their general health and well-being.<sup>1–3</sup> Indeed, mental health practice guidelines in the United States<sup>4</sup> and United Kingdom<sup>5,6</sup> suggest that family-based interventions in FEP can produce better patient outcomes if their family caregivers demonstrate more improved coping and functioning. A systematic review<sup>7</sup> of clinical trials of family intervention in FEP over the past 2 decades, comprising elements of psycho-education and problem-solving, have demonstrated significant improvements in knowledge about mental illness/treatments and reduction in relapse rate. Despite none being found in FEP, a few controlled trials of family intervention such as psycho-education and behavioral management programs for Chinese people with schizophrenia in Hong Kong/China have shown significant effects on patients' symptoms and treatment adherence, family support and illness-related knowledge.<sup>2,8,9</sup> However, these trials showed only modest effects on other clinical outcomes among patients (eg, functioning and insight into illness) and their families (eg, caregiving burden and coping).<sup>3,10,11</sup>

Recognizing limited resources and accessibility to such family programs and families' feeling disempowered/stigmatized by psychiatric services,<sup>5,8</sup> recent research in Western and Chinese populations has increasingly examined the feasibility of self-help programs for family caregivers in psychosis.<sup>2,6,8</sup> Indeed, an increasing body of research indicates that bibliotherapy (therapy in book-form) may overcome many of these limitations, provide information and guidance for caregiving and empower caregivers to identify their health needs and cope in first-time caring for a FEP relative.<sup>9,12,13</sup> The approach requires less intensive training for professionals as facilitators, and provides a flexible, client-directed approach to improve caregivers' coping and negative illness perceptions.<sup>14,15</sup>

This can be helpful for Chinese family caregivers who are usually highly tolerant, supportive and willing to be involved in all aspects of care for a FPP relative.<sup>8,16</sup>

Very few controlled trials of bibliotherapy have been undertaken with caregivers of people with FEP in Western countries.<sup>7</sup> A randomized controlled trial (RCT) of family bibliotherapy in Australia reported an increase in carers' positive caregiving experience, reduced expressed emotion and psychological distress over a 16-week follow-up.<sup>17</sup> Currently, only 1 bibliotherapy study has been conducted with caregivers in Chinese or Asian populations, with an improved caregiving experience to depressed patients at 1-month follow-up.<sup>18</sup>

Bibliotherapy, with self-help problem-solving supported from clinicians/professions, may be appropriate and beneficial to Chinese families who are often reluctant to seek help due to strong perceptions of stigma and unwillingness to disclose family problems to outsiders/therapists.<sup>19,20</sup> Similar to findings in the West, Chinese caregivers often feel responsible for the young family member's illness and grieve about losing their "normal" child with independent and satisfactory daily living.<sup>14,21</sup>

In this study, we aimed to evaluate the effects of clinician-supported problem-solving bibliotherapy (CSPSB) for Chinese family caregivers of people with FEP on caregiving experience and burden, and its impact on patient outcomes. Our primary hypotheses were that the CSPSB group, compared to usual outpatient-and-family support (UOFS), would demonstrate a greater reduction in burden and improved caregiving experience, at 1-week and 6- and 12-month follow-up. Secondary hypotheses were that compared with the UOFS group, the CSPSB group would have significantly greater improvements in caregivers' social-problem-solving skills and patients' psychotic symptoms, functioning and re-hospitalization rates (number and duration) over the 12-month follow-up.

## Methods

An RCT of a CSPSB, with a repeated-measures control-group design, was conducted in Hong Kong between January 2014 and October 2015. A CONSORT flow diagram of the study procedure is presented in [figure 1](#).

### Participants

Patients diagnosed with FEP (not >6 mo onset of illness) by experienced psychiatrists according to the DSM-IV-TR criteria (high diagnostic stability)<sup>22</sup> were selected randomly by 1 researcher (W.T.C.) from the patient lists (in alphabetical order of surnames) of 2 regional outpatient clinics (OPCs) for early psychosis service. After initial screening, 460 of about 1000 FEP patients attending the OPCs met the study inclusion criteria below; 116 of them on the patient lists were selected using computer-generated random

numbers. With their consent, informed consent was also obtained from 1 main family caregiver to participate.

The inclusion criteria for caregivers were: (a) aged 18 years or above, (b) able to communicate in written and conversational Chinese/Cantonese, (c) first-time caregiver (for mental illness), and (d) lived with and provided most of the daily care and support for the patient with FEP. Exclusion criteria for caregivers were suffering from an acute episode of mental illness and recipients of specialized family interventions. Inclusion criteria for patients were: (a) diagnosis of FEP<sup>22</sup> and without co-morbidity of another mental illness at baseline; and (b) first contact with mental health services. Exclusion criteria for patients included relapse/re-hospitalization before randomization and receiving another family intervention.

### Randomization

A computer-generated randomization list was obtained from a statistician, in blocks of 10 and given to a research assistant for recruitment. One researcher allocated the next available number on the trial entry, and the code was concealed until completion of the baseline measurements to avoid allocation bias. After random selection and baseline measurement, caregivers were randomly assigned into CSPSB or UOFS using computer-generated random numbers by the statistician.

### Sample Size and Power

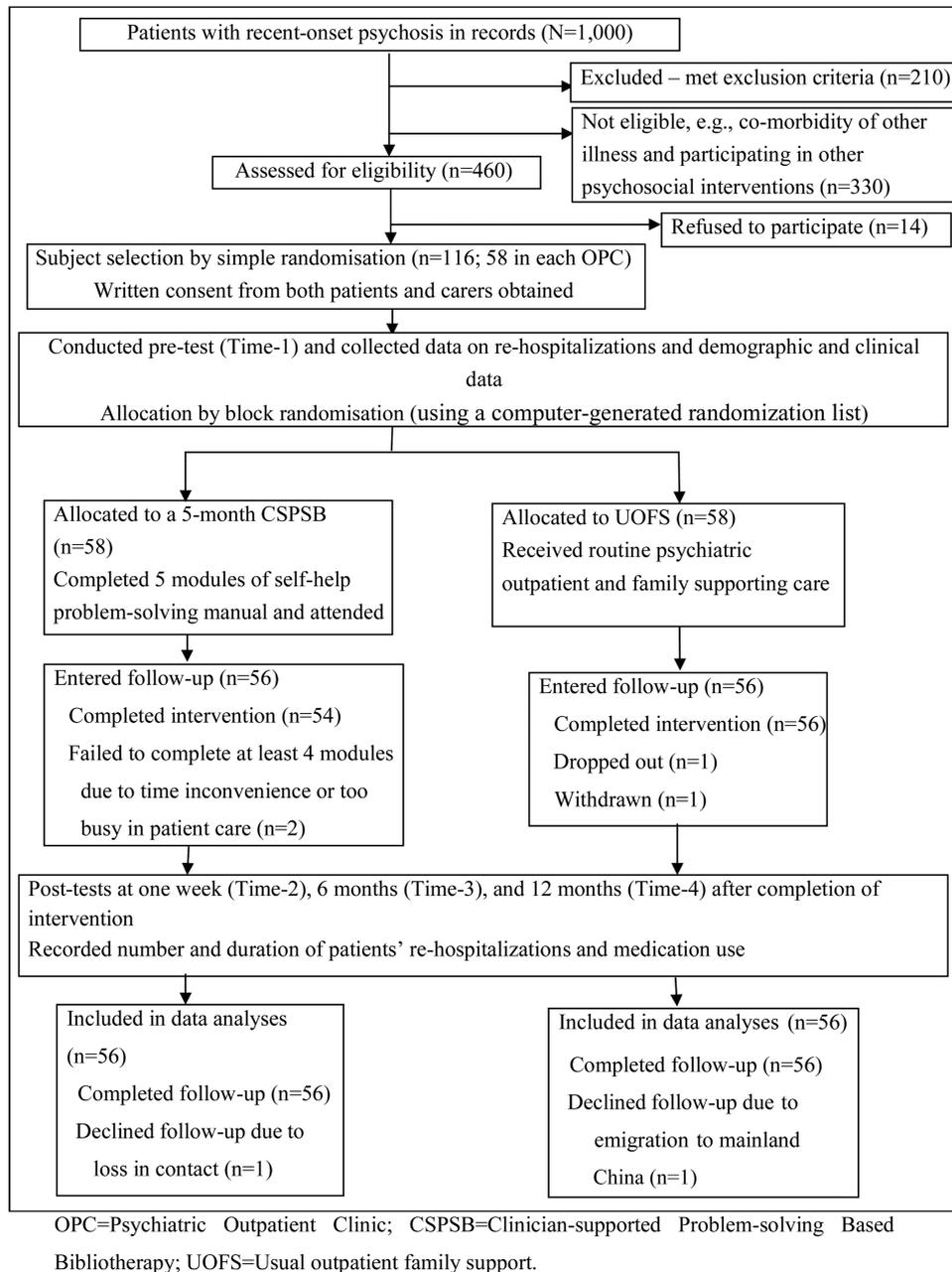
Sample size was calculated a priori. Based on 2 clinical trials of family intervention in FEP (China and Australia),<sup>17,23</sup> the effect sizes on family burden were 0.60 and 0.58 and re-hospitalization (days of hospital-stay) were 0.68 and 0.56, respectively. Therefore, we estimated that 58 family dyads per intervention with 15% expected attritions were required to provide 80% power (2-sided,  $P < .05$ ) to detect a statistically significant difference on changes in family burden of 1.5 points ( $SD = 2.7$ )/re-hospitalization rate of 4.5 d/mo ( $SD = 8.7$ ),<sup>24</sup> indicating a more conservative effect size (0.50) than the above-mentioned trials.

### Outcome Measures

Study outcomes were assessed by a research assistant who received 1 day's training by the researchers and assessed for inter-rater reliability of scale ratings ( $ICC = 0.88-0.95$ ).

**Primary Outcome Measures.** These measures were burden and experience of caring, assessed by the Family Burden Interview Schedule (FBIS)<sup>25</sup> and Experience of Caregiving Inventory (ECI),<sup>26</sup> respectively.

The 25-item FBIS<sup>25</sup> consists of 5 domains of perceived burden (eg, family finance, leisure, interaction, and physical/mental health) rated on a 3-point Likert scale (from 0—"no burden" to 2—"severe burden"). The Chinese



**Fig. 1.** The flow diagram of the procedure of this controlled trial for the 2 study groups, according to the latest version of CONSORT statement. OPC = Psychiatric Outpatient Clinic; CSPSB = Clinician-supported Problem-solving Based Bibliotherapy; UOFS = Usual outpatient family support.

version demonstrates satisfactory internal consistency (Cronbach's  $\alpha = .78-.88$ ) and adequate test-retest response stability (ICC = 0.83–0.92).<sup>27</sup>

The 66-item ECI is based on transactional model of stress-appraisal-coping.<sup>26</sup> The ECI has 2 subscales: positive (14 items) and negative (52 items) aspects of caregiving. Items are rated on a 5-point Likert scale (0—"never" to 4—"nearly always"), with a higher total score indicating more negative appraisal of caregiving experiences. The Chinese version has satisfactory content validity and internal consistency (Cronbach's  $\alpha = .80$ ).<sup>28</sup>

**Secondary Outcome Measures.** These measures were caregivers' social-problem-solving skills (Social-Problem-Solving Inventory-Revised:Short-version [SPSI-R:S]),<sup>29</sup> and for patients, their functioning (Specific Level of Functioning scale [SLOF]),<sup>30</sup> severity of psychotic symptoms (Positive and Negative Syndrome Scale [PANSS])<sup>31</sup> and re-hospitalization rates.

The 25-item SPSI-R:S contains 2 domains: problem-solving style and problem-solving orientation (positive/negative).<sup>29</sup> It is rated on a 5-point Likert scale (0—"not-at-all true" to 4—"extremely true"). The scale has satisfactory

internal consistency (Cronbach's  $\alpha = .68-.81$ ) and concurrent validity with coping scales in Chinese adults.<sup>32</sup>

The 43-item SLOF is rated on a 5-point Likert scale (from 1—"totally dependent" to 5—"highly self-sufficient") along 3 functional areas for psychotic patients: self-maintenance, social functioning, and community-living skills.<sup>30</sup> The Chinese version demonstrates satisfactory content validity and internal consistency (Cronbach's  $\alpha = .88-.96$ ).<sup>9</sup>

The 30-item PANSS assesses the severity of psychotic symptoms on 3 subscales: positive symptoms, negative symptoms and general psychopathology.<sup>20</sup> The scale is scored on a 7-point Likert scale (from 1—"absent" to 7—"extreme") and has a high concurrent validity with the Brief Psychiatric-Rating Scale (Pearson's  $r = .85-.90$ ) and internal consistency (Cronbach's  $\alpha = .88-.91$ ).<sup>32</sup>

The number and duration (d/mo) of patients' re-hospitalizations over the previous 6 months and dosages (in haloperidol equivalents)<sup>33</sup> and adherence rates of psychotropic medications were obtained from patient records.

### Treatments

*Clinician-Supported Problem-Solving Bibliotherapy.* The CSPSB (in addition to UOFS) completed a problem-solving-based bibliotherapy manual developed by McCann et al,<sup>16,18</sup> translated into Chinese and validated by the research team and 6 experts on psychiatric rehabilitation. The manual adopted the self-directed problem-solving approach to FEP caregiving,<sup>34</sup> and involved guided-learning by reading written information and references, enabling caregivers to solve their caregiving problems "step-by-step" ([supplementary material](#)). Specific Chinese cultural considerations were added in the manual, including stigma towards mental illness, open disclosure/discussion of intense negative feelings and family needs, reinforcing interdependent/collective behaviors among family members in caregiving, and emphasis on practical aids for patient/family affairs.<sup>8,20,23</sup>

Each caregiver worked independently through 5 CSPSB modules over 20 weeks. The first author (WTC) provided two 1-hour group sessions (each comprising 15–18 caregivers) during the first and second week as an orientation to psychosis and its treatment, facilitating caregivers' engagement in the intervention. The caregivers were motivated to enhance self-care with Module 1 (eg, self-reflecting own emotions/well-being and identifying key areas of caregiving burden and adaptive problem-solving approach in caregiving), and complete 1 module per month. Three review sessions (1.5-hour sessions in weeks 6, 12, and 20 with WTC) in groups were held in the OPCs to check their progress in module completion (30 min) and clarify important problems/difficulties in understanding the material (45 min). A trained research assistant also telephoned the caregivers biweekly (8–10 telephone calls over 20 wk) to monitor their progress by asking a standardized set of 10 questions (eg, "How

was your completion of the module (1 to 5)?," "What is your planning ahead to keep up with the schedule?," and "Are there any difficulties encountered?"). The research assistant recorded all replies to the 10 questions from the caregivers and brought their mentioned difficulties to the review sessions for discussion. In the telephone calls, the research assistant only provided advice for the caregivers on 2 aspects: (a) encouraging them to continue with the modules on schedule and (b) referring them to crisis intervention or other relevant services if immediate support/help needed (eg, indicating suicidal and self-harm intents/behaviors).

Half of the review sessions and telephone calls were audio-taped and scored by 2 researchers to monitor treatment fidelity using a checklist based on the NIH-Behavior-Consortium recommendations.<sup>23</sup> The levels of treatment fidelity were very satisfactory (91.5%–95.8%).

*Usual Outpatient and Family Services.* UOFS provided at the OPCs (for both study groups) included psychiatric consultations and treatment to patients by a psychiatrist (every 4–8 wk), brief education sessions (monthly/bimonthly) about mental illness and its treatment by psychiatric nurses, social welfare and financial aid services by a social worker, and training in social/interpersonal skills for patients and caregivers by an occupational therapist (monthly). Patient/family counseling was also provided by a clinical psychologist, as needed. In addition, an information booklet was provided about looking after caregiver's well-being.

### Procedure

Ethical approval was obtained from the Research Ethics Committee of The Hong Kong Polytechnic University and the OPCs (HSEARS20140218003). After obtaining written consent from family dyads, the trained research assistant (who was blind to group assignment) administered the baseline measurements (Time-1) before group allocation, and 3 outcome measurements in the OPCs at 1 week (Time-2), 6 months (Time-3) and 12 months (Time-4) post-intervention. Patients' re-hospitalization rates (frequency and d/mo) and psychotropic medications and their adherence rates were also examined.

### Statistical Analyses

All outcome and sociodemographic data were screened and analyzed using IBM's SPSS, version 20.0. Homogeneity of the 2 study groups' sociodemographic characteristics and baseline outcome measure scores was checked with independent sample *t* (2-tailed) or Chi-square tests. Based on an intention-to-treat basis and no violation of assumptions of multivariate analyses,<sup>24</sup> a repeated-measures mixed-model MANOVA test was performed for the outcome variables (FBIS, ECI, SPSI-R:S, SLOF, PANSS, total amount [dosage] of psychiatric medications, and

re-hospitalization rates) to determine the interactional (Group  $\times$  Time) treatment effects, and univariate between-group effects across time. If between-group effects were found significant on the outcome measure(s), Helmert's contrasts tests were used to identify where the significant differences on each outcome mean score(s) were located.<sup>24</sup> For outcomes showing significant between-group differences over time, the mean scores of each outcome in the CSPSB were compared between clinics, using 1-way ANOVA test. The level of statistical significance was set at 0.05, except univariate ANOVA tests for between-group effects at 0.006 (using a Bonferroni adjustment).<sup>24</sup>

## Results

### *Participant Flow and Sample Characteristics*

One hundred thirty of the 460 eligible patients were randomly selected and contacted by the first author; 116 patients agreed to participate (ie, response rate = 89%). One hundred ten families (94.8%) completed the intervention and follow-up; 2 families in the CSPSB and UOFS withdrew, or were lost to contact at the first post-test (Time-2), and were not included in the final data analysis (figure 1). While 2 caregivers discontinued their participation from the CSPSB, 54 (93.1%) completed  $\geq 4$  modules, 2 orientation and  $\geq 2$  review sessions ( $>80\%$  of the CSPSB). Reasons for withdrawal or discontinuing from CSPSB participation/the study were: insufficient time to attend ( $n = 2$ ), patient's mental state worsened ( $n = 1$ ), and lack of interest in participation ( $n = 2$ ). During the telephone calls, 4 caregivers in the CSPSB were referred to family counseling ( $n = 2$  at the 8th and 10th week of intervention, respectively) and suicidal prevention service ( $n = 2$  at the 16th week of intervention).

The sociodemographic characteristics of caregivers and patients ( $n = 58$  in each group) are summarized in table 1. Caregivers' mean age was about 50 years (CSPSB:  $M = 49.1$ ,  $SD = 9.8$ ; UOFS:  $M = 50.2$ ,  $SD = 9.0$ ) and about two-thirds were female. Their relationships with patients were mainly parent (43.0% and 44.8%), spouse (both 19.0%), or child (both 19.0%).

The mean age of the patients was about 26 years. More than half (57.0% and 58.6%) were male and the majority (82.8% and 84.5%) were taking a low/medium dosage of antipsychotics (haloperidol equivalents = 2.5–4.9 mg/d).<sup>33</sup> Over 80% were on oral medication only, mainly typical (32.8% and 31.0%) and atypical/blended (48.3% and 50.0%) antipsychotics. On average, 2 family members lived with the patients, and the duration of illness was 4 months (ranged 1–6 mo). The duration of untreated psychosis was about 2 months (range 0–4 mo).

There were no significant differences between the 2 groups in any sociodemographic characteristics ( $P > .11$ ) and no significant correlations (Spearman's  $r < .12$ ) between any outcome variables at baseline.

### *Treatment Effects*

There were no significant differences in any of the outcome mean scores between the 2 groups at baseline ( $P > .13$ ), thus negating the need for co-variance analysis. Results of the MANOVA indicated a statistically significant difference between groups on the combined outcome variables,  $F(6,110) = 6.82$ ,  $P = .001$  (Wilks'  $\lambda = 0.91$ ; a large effect with partial  $\eta^2 = 0.24$ ).<sup>24</sup> As indicated in table 2 (with independent  $F$  values for MANOVA), there was a statistically significant interaction (Group  $\times$  Time) of treatment effects for the CSPSB (with large effect sizes),<sup>24</sup> with significantly greater improvements in caregivers' ECI [ $F(1,110) = 7.21$ ,  $P = .0008$ , partial  $\eta^2 = 0.28$ ] and its subscale scores [Positive experiences:  $F(1,110) = 5.68$ ,  $P = .005$ ; Negative experiences:  $F(1,110) = 7.80$ ,  $P = .0005$ ] and FBIS [ $F(1,110) = 6.86$ ,  $P = .001$ , partial  $\eta^2 = 0.23$ ] and its 5 subscales [ $F(1,110) = 5.12$ – $7.13$ ,  $P = .005$ – $.0008$ ]. The CSPSB group also had significant greater improvements in patients' SLOF score [ $F(1,110) = 6.95$ ,  $P = .003$ , partial  $\eta^2 = 0.25$ ], PANSS score [ $F(1,110) = 5.98$ ,  $P = .005$ , partial  $\eta^2 = 0.20$ ], and duration of re-hospitalizations [ $F(1,110) = 5.78$ ,  $P = .005$ , partial  $\eta^2 = 0.19$ ].

The Helmert's contrasts tests results indicated that there were statistically significant differences between the CSPSB and UOFS on the changes in mean scores of:

- Family caregiving experience (ECI) and burden (FBIS) of the CSPSB improved significantly at Time-2 (mean difference = 11.7 and 4.4,  $P = .001$  and  $.008$ , respectively), Time-3 (mean difference = 27.7 and 9.4,  $P = .0008$  and  $.001$ , respectively) and Time-4 (mean difference = 29.7 and 12.8,  $P = .0006$  and  $.0008$ , respectively), compared to the UOFS.
- Patient functioning (SLOF score) in the CSPSB increased and the severity of their psychotic symptoms (PANSS score) reduced significantly at Time-3 and -4, compared to the UOFS (mean difference = 20.4 and 44.8,  $P = .001$  and  $.0008$  for SLOF; mean difference = 24.0 and 30.0,  $P = .005$  and  $.001$  for PANSS, respectively).
- Duration of patients' re-hospitalizations in the CSPSB decreased significantly at Time-3 and -4 (mean difference = 6.0 and 11.4,  $P = .003$  and  $0.001$ , respectively), compared to the UOFS.

There were no significant differences in the dosages of antipsychotics ( $P = .09$ ; table 2), types of family/patient services utilized ( $P = .13$ ) and medication adherence rates ( $P = .15$ ) across measurements between groups. The patient and family support services utilized by the CSPSB and UOFS participants over the follow-up included: individual patient ( $n = 30$  and  $21$ ; median = 6 and 8 times, range 3–10 and 2–11, respectively) and family counseling ( $n = 32$  and  $24$ ; median = 8 and 5 times, range = 4–13 and 2–9, respectively), supportive employment ( $n = 30$  and  $31$ ; median = 7 and 5 times, range = 4–10 and 2–7, respectively),

**Table 1.** Characteristics of Family Caregivers and Patients at Recruitment ( $N = 116$ )

Characteristics	CSPSB ( $n = 58$ )		UOFS ( $n = 58$ )		Test Value <sup>a</sup>	<i>P</i>
	<i>f</i>	%	<i>f</i>	%		
<b>Family Caregivers</b>						
Gender						
Female	38	65.5	37	63.8	1.32	.32
Male	20	34.5	21	36.2		
Age (y)	$M = 49.1, SD = 9.8$		$M = 50.2, SD = 9.0$		1.17	.34
20–29	7	12.1	7	12.1		
30–39	16	27.5	14	24.1		
40–49	23	39.7	24	41.4		
50 or above	12	20.7	13	22.4		
Education level						
Primary school or below	10	17.2	11	19.0	1.52	.29
Secondary school	38	65.5	39	67.2		
University or above	10	17.2	8	13.8		
Relationship with patient						
Child	11	19.0	11	19.0	1.48	.30
Parent	25	43.0	26	44.8		
Spouse	11	19.0	11	19.0		
Others (eg, sibling & grandparent)	11	19.0	10	17.2		
Monthly household income (HK\$) <sup>b</sup>	$M = 15\,420, SD = 2995$		$M = 16\,340, SD = 3195$		2.30	.11
5000–10 000	9	15.5	8	13.8		
10 001–15 000	19	32.8	20	34.5		
15 001–25 000	22	37.9	20	34.5		
25 001–35 000	8	13.8	10	17.3		
<b>Patients</b>						
Gender						
Male	33	56.9	34	58.6	1.20	.31
Female	25	43.1	24	41.4		
Age (y)	$M = 25.8, SD = 8.8$		$M = 26.5, SD = 8.5$		1.10	.38
18–25	28	48.2	27	46.5		
26–30	22	38.0	22	38.0		
31–40	8	13.8	9	15.5		
Duration of illness (mo)						
1–2	19	32.8	20	34.5	1.12	.35
3–4	25	43.1	25	43.1		
5–6	14	24.1	13	22.4		
Types of psychotropics						
Atypical antipsychotic	18	31.0	17	29.3	1.40	.20
Typical antipsychotic	19	32.8	18	31.0		
Anti-depressant	8	3.8	7	12.1		
Anxiolytic	3	5.2	4	6.9		
Blended mode <sup>c</sup>	10	17.3	12	20.7		
Dosage of medication <sup>d</sup>						
High	10	17.2	9	15.5	1.20	.32
Medium	24	41.4	24	41.4		
Low	24	41.4	25	43.1		

Note: CSPSB, Clinician-supported Problem-solving Based Bibliotherapy; UOFS, Usual outpatient family support.

<sup>a</sup>Independent sample *t* test ( $df = 1$ , 2-tailed) or Chi-square Good-of-fit test was used to compare the sociodemographic variables of families between 2 study groups.

<sup>b</sup>US\$1 = HK\$7.8.

<sup>c</sup>Blended mode of medication mainly included combined use of atypical and typical antipsychotics, or an antipsychotic and anti-depressant.

<sup>d</sup>Dosage levels of antipsychotic medication were compared with the average dosage of medication taken by patients with schizophrenia in Haloperidol equivalent mean values.<sup>33</sup>

social skills training ( $n = 28$  and  $26$ ; median =  $8$  and  $6$  times, range =  $4$ – $11$  and  $2$ – $10$ , respectively), and social welfare service ( $n = 45$  and  $48$ ; median =  $9$  and  $8$  times, range =  $4$ – $14$  and  $4$ – $16$ , respectively); all patients ( $n = 56$  in

both groups) received psychiatric consultation and brief education sessions on mental illness (median =  $4$  and  $7$  times, range =  $2$ – $6$  and  $5$ – $10$ , respectively). The average medication (antipsychotic) adherence rates at Times 1–4

**Table 2.** Outcome Measure Scores at Pre-Test and 3 Post-Tests and MANOVA Test (Group × Time) Results (N = 116)

Instrument	UOFS (n = 56)												Effect size η <sup>2</sup>					
	Time-1			Time-2			Time-3			Time-4								
	M	SD		M	SD		M	SD		M	SD							
CSPSB (n = 56)																		
ECI <sup>a</sup> (0–204) <sup>b</sup>	131.1	19.1	118.2	21.2	105.5	20.8	99.3	19.2	133.1	19.9	129.9	22.0	133.2	24.1	129.0	25.0	7.21***	0.28
Positive experiences	31.1	3.2	32.2	4.1	33.4	3.6	34.3	3.6	31.4	3.8	30.1	4.8	29.5	4.8	29.1	4.6	5.68**	0.21
Negative experiences	99.0	4.9	86.0	4.0	72.1	3.2	65.0	3.0	101.7	5.8	99.8	4.9	103.7	7.3	99.9	8.6	7.80***	0.32
FBIS (0–50)	30.1	6.8	26.8	8.6	23.1	9.8	20.3	10.0	30.6	7.6	31.4	9.2	32.5	9.8	32.8	10.8	6.86***	0.23
Family finance	9.2	1.1	8.3	1.0	7.4	0.9	6.2	0.9	9.5	1.3	9.3	1.2	9.4	1.1	9.5	1.5	7.01***	0.25
Leisure and activities	5.0	1.0	4.8	0.9	4.2	0.8	4.0	0.7	5.1	1.3	5.4	1.0	5.9	0.9	6.0	1.4	5.28**	0.2
Family interactions	2.7	0.8	2.3	0.7	2.1	0.7	1.8	0.6	2.9	0.9	3.2	0.8	3.4	0.9	3.6	1.0	5.12**	0.18
Physical health	8.5	1.4	8.0	0.9	7.1	0.9	6.5	0.7	8.7	1.3	8.9	1.2	9.1	1.3	9.5	1.2	6.98***	0.24
Mental health	4.7	0.7	3.4	0.7	2.3	0.4	1.7	0.5	4.4	0.6	4.6	0.8	4.7	0.9	4.2	0.8	7.13***	0.26
SPSI-R:S (0–100)	52.3	9.1	57.5	8.9	63.4	9.8	69.7	10.5	53.9	8.1	54.7	9.7	54.9	10.8	54.0	9.5	3.22	0.04
SLOF (43–215)	129.5	18.9	135.8	20.0	150.7	21.1	170.8	22.9	129.8	19.7	129.0	24.6	130.3	25.0	126.0	28.0	6.95***	0.25
PANSS (30–210)	132.1	21.2	123.4	20.3	119.0	26.0	116.1	21.1	131.9	21.0	140.1	28.2	143.0	21.4	146.1	30.3	5.98**	0.2
Re-hospitalization																		
Number	1.1	1.0	1.0	1.0	0.9	1.0	0.8	1.0	1.0	1.1	1.3	1.1	1.3	1.2	1.3	1.4	3.01	0.05
Duration (d) <sup>c</sup>	15.3	4.8	15.0	9.8	12.0	8.2	11.0	10.8	14.2	8.5	19.0	9.8	18.0	9.8	22.4	12.1	5.78**	0.19
Medication <sup>d</sup>	8.4	4.3	8.0	6.3	7.9	5.4	8.2	5.0	8.2	3.8	8.8	4.6	9.5	6.1	10.0	6.9	3.26	0.04

*Note:* OPC, Psychiatric Outpatient Clinic; CSPSB, Clinician-supported Problem-solving Based Bibliotherapy; UOFS, Usual outpatient family support; ECI, Experience of Caregiving Inventory; FBIS, Family Burden Interview Schedule; SPSI-R:S, Social Problem-Solving Inventory-Revised: Short version; PANSS, Positive and Negative Syndrome Scale; SLOF, Specific Level of Functioning Scale. Time 1 = baseline measurement at recruitment; Time 2 = 1 week after completion of intervention; Time 3 = 6 months after completion of intervention; Time 4 = 12 months after completion of intervention.

<sup>a</sup>For ECI, the higher the mean score the more negative the appraisal of family carers to their caregiving experiences.

<sup>b</sup>Possible range of scores of each scale indicated in parenthesis.

<sup>c</sup>Duration of re-admissions in a psychiatric hospital or in-patient unit at Times 1, 2, 3, and 4, in terms of days of hospital stay over the past 6 months.

<sup>d</sup>Medication scores were based on the converted haloperidol equivalents as recommended by Bezchlibnyk-Butler, Jeffries and Viran.<sup>33</sup>

\**P* < .01, \*\**P* < .005, \*\*\**P* < .001.

were 69.5%–89.8% (range 60.1%–95.2%) in the CSPSB and 70.8%–83.3% (range 58.2%–89.1%) in the UOFS.

Comparisons of mean scores on caregiver and patient outcomes at Times 2–4 between the CSPSB subgroups in terms of availability of other family caregiver(s) and study sites (OPCs) indicated no significant differences on any outcome scores at all post-tests between the subgroups ( $P > .15$ ). The CSPSB indicated consistent greater reduction in the percentages of patients being re-hospitalized over the 4 measurement periods than the UOFS group (55.2% and 51.0% [Time-1], 39.0% and 40.4% [Time-2], 37.3% and 43.1% [Time-3], and 32.5% and 40.0% [Time-4]). However, these percentages were not significantly different between-group across time (Kruskal-Wallis test,  $P = .10$ ).

## Discussion

### Primary Outcomes

Given relatively less available usual family support services than many Western countries were provided at the OPCs, the 5-month CSPSB demonstrated very positive effects on family caregiving at 12-month follow-up. The primary hypotheses concerning the effects of bibliotherapy on the caregiving experience and burden were supported, with the CSPSB group reporting significantly greater and substantive improvements in positive appraisals of caregiving experiences (ECI) and aspects of family burden at 12-month follow-up, than the UOFS. The CSPSB also experienced a greater reduction in negative appraisals of caregiving and more positive experiences of family relationships/communication with their FEP relative than the UOFS group. The McCann and colleagues<sup>18</sup> RCT, using a similar bibliotherapy manual, indicated partial benefits for caregivers' appraisals of caring for their FEP relative but the benefits were only on 2 aspects of appraisals ("positive personal experiences" and "need to back-up" subscales), and with short-term follow-up (16 wk). In addition, Gleeson and colleagues<sup>35</sup> RCT of family CBT-based relapse prevention program demonstrated a similar positive effect in a wide range of caregivers' appraisals of their caring experiences as shown in the present study over 2-year follow-up. Nevertheless, the relapse prevention program was more resource-intensive and lengthy and did not have any effect on caregiving burden.

The bibliotherapy in the present study also demonstrated significant benefit for caregivers' burden of care. The CSPSB group indicated significantly greater improvements in their family burden on finance, social activities/relationships and general health, than the UOFS group over the 12-month follow-up. In contrast with other bibliotherapy programs,<sup>18,35,36</sup> the CSPSB could provide prompt post-intervention benefits to the caregivers in coping with their initial negative perception of the illness and family burden associated with their relative's

FEP diagnosis and newly-adopted caregiving role, which may be due to the strong interconnectedness of families in Hong Kong; and these benefits could help sustain them for a longer period of follow-up.

### Secondary Outcomes

The CSPSB also demonstrated a number of positive effects for patients with FEP, including reduced severity of psychotic symptoms, improved functioning and shorter re-hospitalizations at 6- and 12-month follow-up. Whilst few family interventions for people with FEP produce significant and consistent beneficial effects on patients' functioning and psychotic relapse,<sup>1-3</sup> these favorable findings may be attributable to the experiential learning, self-help and user-friendly approach of the bibliotherapy in improving caregivers' experience of, and skills in, caring. It may also equip caregivers to better manage patients' FEP and detect the signs of relapse and engage in help-seeking earlier. Nevertheless, it is noteworthy that over one-third of patients were hospitalized during follow-up, although slight reductions in the average number of re-hospitalizations occurred in the CSPSB. This may suggest the usual outpatient care provided at the clinics is not adequate/effective in these patients' community-based rehabilitation.

There was no significant difference between the 2 study groups on social problem-solving ability, although a gradual improvement in this ability was noted in the CSPSB. A possible explanation for this non-significant result is that the problem-solving orientation/style, which is correlated with the individual's complex social situation and family environment, can be changed and thus evaluated only in the longer-term.<sup>29,34</sup> To establish a rational and positive problem-solving ability in caregivers, more emphasis may need to be added to interpersonal/communication skills training in order to strengthen their social interactions and trusting relationships with patients.

### Study Retention and Dose of Intervention

Caregivers' rates of completion of the CSPSB (93%) and overall attrition (5%) in this study are much more favorable than other family/caregiver intervention studies in FEP.<sup>10,18,19,35</sup> There are 4 possible explanations for this high participation/low attrition rate. First, it could be explained by the benefits induced by the problem-solving approach and easy-to-read manual, shorter duration and briefer content of the intervention, regular review sessions and telephone calls, and self-directed approach to module completion at the caregivers' convenience and pace. Second, first-time caregivers might have perceived they were mandatory or had no choice but to participate and complete the intervention, even though the researchers were not employees of the clinics and had discussed the trial to ensure participation was voluntary. In



addition, the caregivers with high income and education might have more time and tend to participate more in the care of their loved one. Third, it might be attributable to a culture of trust and respect for people perceived to be in authority, common in Chinese/Asian populations.<sup>8,16,20</sup> Finally, the high participation rate might be due to the fact that very few tailored or brief and user-friendly family support services have been provided to Chinese caregivers of people with FEP.<sup>7,10,36</sup>

Based on our previous guided self-help family intervention studies,<sup>11,16–18</sup> and feedback from the CSPSB group during the review sessions, completion of 1 module of bibliotherapy per month was found to be appropriate and desirable for caregivers' learning and rehearsals of positive appraisal of caregiving. The review sessions could also help them consolidate what they had learned and clarify questions about the reading materials.

### Strengths and Limitations

This trial was 1 of very few to test the effectiveness of a clinician-supported bibliotherapy in providing family support for patients with FEP,<sup>37,38</sup> the first in Chinese/Asian family caregivers of these patients, and was found to be effective over a medium-term (12 mo) follow-up. The study design, such as clear procedures for recruitment, randomization and data collection and analyses and blinding of the outcome assessor, researchers and clinical staff throughout the study, ensured a high-quality RCT.

There are 3 potentially important limitations to this study. First, the sample was recruited from 2 of 18 outpatient clinics in Hong Kong and the patients experienced FEP for <6 months. Therefore, this selective sample may not be representative of the broader FEP population.<sup>23,39</sup> Second, despite random selection of caregiver participants, most were young (aged 20–49 y) and literate with secondary or higher level of education (>80%) and higher monthly incomes than the local population's average value. The participants' sociodemographic characteristics and/or baseline outcome scores should have been compared with those of the nonparticipants, in order to reveal the representativeness of the sample (ie, generalization of the findings). Last, the use of self-report measures for the caregiver outcomes might induce participants' biased responses to the treatment effects, thus requiring objective measurements to enhance the internal validity.<sup>40</sup>

### Conclusion

This 5-month CSPSB, in addition to the usual family support service, can help these first-time caregivers improve their caregiving experiences and burden of care, and their patients' psychotic symptoms and functioning. These favorable findings warrant further research on this intervention involving family caregivers from different socioeconomic and cultural backgrounds in Asian populations

and over a longer-term follow-up (eg, >2 y), as well as in patients with longer histories of psychosis and/or other comorbid mental health problems.

### Supplementary Material

Supplementary material is available at <http://schizophreniabulletin.oxfordjournals.org>.

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