

The effectiveness of manual-guided, problem-solving-based self-learning programme for family caregivers of people with recent-onset psychosis: a randomised controlled trial with 6-month follow-up

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Contributors:

The Contributions made by the authors for the manuscript include: (1) conception and design of the study: WTC, ALY, JWL, and TWM; acquisition of data: WTC and ALY; analysis and interpretation of data: WTC and TRM (2) drafting the article or revising it critically for important intellectual content: WTC and TRM; and (3) final approval of the version to be submitted: WTC, ALY, JWL, and TWM.

What is already known about the topic

- Recent-onset psychosis is a distressing and disabling mental disorder for both young patients themselves and their first-time family caregivers.
- A few approaches to family intervention in psychosis such as psycho-education have resulted in a few positive patient outcomes, mainly mental state and relapse from illness, but comparatively few caregivers' health outcomes.
- Self-care, coping and problem-solving skills training, which is based on the stress-vulnerability and stress-coping model, have been more frequently adopted in patients

with chronic illnesses, as well as their family carers. Nevertheless, more research should be conducted to prove its positive effects as an early intervention for people with recent-onset psychosis.

What this paper adds

- Self-help, problem-solving-based manual-guided learning programme, or bibliotherapy (in addition to usual care), is more effective to improve family caregivers' and patients psychosocial health conditions in recent-onset psychosis over 6-month follow-up, when compared to usual family support services only.
- Bibliotherapy, significantly improved caregivers' perceived burden and patients' mental state and risk of relapse over a 6-month follow-up. However, caregivers received usual family support service reported a gradual deterioration in most of the patients' and caregivers' outcomes over the follow-up period.
- This manual-guided problem-solving-based self-learning programme can also enhance families' positive experiences and appraisals of first-time caring for their relative with recent-onset psychosis.

Abstract

Background: Family intervention for psychotic disorders is an integral part of psychiatric treatment with positive effects on patients' mental state and relapse rate. However, the effect of such family-based intervention on caregivers' psychological distress and well-being, especially in non-Western countries, has received comparatively much less attention.

Objective: To test the effects of guided problem-solving-based manual-guided self-learning programme for family caregivers of adults with recent-onset psychosis over a 6-month period of follow-up, when compared with those in usual family support service.

Design: A single-centre randomised controlled trial, which was registered at ClinicalTrials.gov (NCT02391649), with a repeated-measures, two-arm (parallel-group) design.

Settings: One main psychiatric outpatient clinic in the New Territories of Hong Kong.

Participants: A random sample of 116 family caregivers of adult outpatients with recent-onset psychosis.

Methods: Following pre-test measurement, caregivers were assigned randomly to one of two study groups: a 5-month self-help, problem-solving-based manual-guided self-learning (or bibliotherapy) programme (in addition to usual care), or usual family support service only. Varieties of patient and caregiver health outcomes were assessed and compared at baseline and at 1-week and 6-month post-intervention.

Results: One hundred and eleven (96%) caregivers completed the 6-month follow-up (two post-tests); 55 of them (95%) completed ≥ 4 modules and attended ≥ 2 review sessions (i.e., 75% of the intervention). The family participants' mean age was about 38 years and over 64% of them were female and patient's parent or spouse. Multivariate analyses of variance indicated that the manual-guided self-learning group reported significantly greater improvements than the usual care group in family burden [$F(1,110) = 6.21, p = 0.006$] and

caregiving experience [$F(1,110)= 6.88, p= 0.0004$], and patients' psychotic symptoms [$F(1,110)= 6.25, p= 0.0003$], functioning [$F(1,110)= 7.01, p= 0.0005$] and number of hospitalisations [$F(1,110)=5.71, p=0.005$] over 6-month follow-up.

Conclusions: Problem-solving-based, manual-guided self-learning programme for family caregivers of adults with recent-onset psychosis can be an effective self-help programme and provide medium-term benefits to patients' and caregivers' mental health and duration of patients' re-hospitalisations.

Keywords: bibliotherapy, family intervention, problem-solving, randomised controlled trial, recent-onset psychosis, self-learning.

What is already known about the topic

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- A few approaches to family intervention in psychosis such as psycho-education have resulted in a few positive patient outcomes, mainly mental state and relapse from illness, but comparatively few caregivers' health outcomes.
- Self-care, coping and problem-solving skills training, which is based on the stress-vulnerability and stress-coping model, have been more frequently adopted in patients with chronic illnesses, as well as their family carers. Nevertheless, more research should be conducted to prove its positive effects as an early intervention for people with recent-onset psychosis.

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- Self-help, problem-solving-based manual-guided learning programme, or bibliotherapy (in addition to usual care), is more effective to improve family caregivers' and patients psychosocial health conditions in recent-onset psychosis over 6-month follow-up, when compared to usual family support services only.
- Bibliotherapy, significantly improved caregivers' perceived burden and patients' mental state and risk of relapse over a 6-month follow-up. However, caregivers received usual family support service reported a gradual deterioration in most of the patients' and caregivers' outcomes over the follow-up period.
- This manual-guided problem-solving-based self-learning programme can also enhance families' positive experiences and appraisals of first-time caring for their relative with recent-onset psychosis.

1. Introduction

With the advent of de-institutionalisation, more than two-thirds of people with recent-onset psychosis (up to the first 6-12 months of illness) in Western and Asian countries are mainly resided in the community and being taken care by their families; whereas, both patients and family caregivers much depend on access to community patient/family support services (Chan, 2011, Pharoah et al., 2010). Carers of a family member with psychotic disorders, particularly first-episode or recent-onset psychosis, are confronted by varying degrees of physical and psychosocial demands in association with unpredictable and abnormal behaviours of the patient and social stigma and discrimination regarding mental illness (Chien and Chan, 2013). Recent systematic reviews suggest that psycho-education programmes for patients with psychotic disorders can enhance their knowledge and insight into the illness and coping with their psychotic symptoms, thus improving prognosis (Xia, Merinder and Belgamwar, 2011; Xia, Zhao and Jayaram, 2013).

However, there has not yet been adequate care and attention to the family carers' health and well-being while these caregivers are often an important source of support and facilitation for these patients' treatment and rehabilitation. Mental healthcare or psychiatric treatment guidelines in both the US and UK suggest that family-based intervention can be an integral of a community-based rehabilitation programme to produce significant positive patient outcomes in early psychosis whenever their family caregivers can improve in coping with their caregiving role and psychosocial functioning (Lehman et al., 2004; The National Collaborating Centre for Mental Health, NICE, 2009). Research evidence from the West has demonstrated the clinical efficacy of a few approaches to family intervention, especially psycho-education and behavioural or crisis management programmes, in reducing patients' relapses from their psychotic disorders (Berglund, Vahlne and Edman, 2003, Petrakis, Oxley and Bloom, 2013).

Recognising that many families may find it difficult to regularly participate in psycho-education or other face-to-face interventions because of time constraints and feeling disempowered or stigmatised by the formal mental health services (Lee et al., 2006), a growing body of research has examined the feasibility of self-help programmes for families caring for a patient with psychotic disorders in Western countries (Edwards and McGorry, 2002, Marshall and Rathbone, 2011). A structured self-help, educational programme may empower caregivers (or service users) to identify their own life problems and needs and minimise professional input, as evidenced in other family support programmes for people with chronic physical and terminal illness such as frailty, stroke and cancer (Foster et al., 2015, Savundranayagam et al., 2011, Valeberg et al., 2013). While there is no practice guideline available in Hong Kong and China for schizophrenia care, the UK Schizophrenia Guidelines (The NICE, 2009) also suggest that ethnically adapted family intervention in psychotic disorders should be designed and evaluated on its benefits to patients' mental health conditions and illness relapse, as well as their caregivers' negative caregiving experiences and distress. This can enable both patients and caregivers to better engage with the intervention. Therefore, more research on an effective approach to family intervention is highly recommended to improve the standard/quality of current community-based rehabilitation in recent-onset psychosis.

Recent systematic reviews on controlled trials of family-based interventions in early psychosis over the past two decades (especially when comprising psycho-education, stress management and problem solving) indicate remarkable improvements in knowledge of mental illness and/or medication adherence and patients' re-hospitalisations (Onwumere, Bebbington and Kuipers, 2011, Cuijpers et al., 2010). However, these clinical trials showed non-observable or little effects on other patients' (e.g., psychotic symptoms and functioning)

and families' outcomes (e.g., caregiving burden and coping effectiveness), in particular over the longer-term (e.g., >3 months).

Moreover, increasing clinical research and practice evidences (e.g., Addington et al., 2001; Ministry of Health and Long-term Care, 2011) suggest that the potential therapeutic components of family intervention are closely related to more effective coping of family members with high levels of burden and demands for patient care in early stage of psychosis. These components include preparedness and competence for caregiving, adaptive functioning, understanding about the illness and its relapse prevention, and empowerment and problem-solving ability (Chien and Bressington, 2015, Chien and Thompson, 2014). Therefore, it is necessary to examine and identify any effective intervention approach for family caregivers in recent-onset psychosis to improve their caregiving experience and well-being, as well as their patients' mental condition and functioning.

An increasing amount/body of research has been found on the feasibility and benefits of self-help programmes for family carers of patients with serious mental health problems (e.g., anxiety disorders, major depression and substance misuse), whose needs have not yet been adequately addressed by routine mental healthcare services (Cuijpers et al., 2010, Chien and Chan, 2013). Structured and manual guided self-help programmes may overcome limitations of insufficient resources and trusting therapist-client relationship in current family support services and also enhance the underused empowerment of caregivers to identify their health needs and cope with their distress in caring for a relative with recent-onset psychosis, particularly being their first time of adopting this caregiving role. Bibliotherapy, being a kind of self-help programme for service users, adopts guided book reading for providing information, guidance and insight into caregiving and emphasises problem-solving approach to offer strategies in identifying and resolving their life problems (Campbell and Smith, 2003, McKenna, Hevey and Martin, 2010). By empathising and personally identifying with a

unique character in the prescribed reading (case study) with problem-solving practices, the caregiver can undergo some channels of psychological catharsis by inducing hope and relieving emotional frustration and turmoil (Fanner and Urquhart, 2008).

Indeed, there is preliminary evidence on the positive effects of bibliotherapy for people with some kinds of mental health problems, such as affective and learning disorders, in the contexts of healthcare services and schools (Shechtman and Nir-Shfir, 2008, Snowball, 2005). Its benefits are mainly on improving participants' problem-solving ability, emotional regulation and psychosocial functioning. A recent small-scale controlled trial has provided evidence on the effect of a family bibliotherapy programme in first-episode psychosis on enhancing the families' positive caregiving experiences and reducing their expressed emotion and psychological distress over a 16-week follow-up (McCann et al., 2013).

It is also commonly believed that a problem-solving, self-help educational programme may also meet the practical (instrumental) needs of Chinese family caregivers of adults with recent-onset psychosis as Chinese people holding strong beliefs that they should overcome their life difficulties and psychological distress of themselves and their relatives by self-discipline and regulation, resolution and perseverance (Chien and Norman, 2009). While manual-guide, problem-solving-based self-learning programme (or bibliotherapy) requires less manpower and training as a facilitator and provides a client-directed and dynamic and flexible approach for these caregivers to prepare for their caregiving role and tasks, its five modules assist in combating negative illness perceptions and emotional regulation that may benefit both caregivers' and patient's mental well-being and accelerate patient's recovery (McCann et al., 2011, Patel et al., 2014). Self-help, problem-solving-based self-learning programme can be appropriate and beneficial to Chinese/Asian families who are often passive and unwillingness to seek help from unfamiliar people such as professionals and therapists during traditional family therapy. This may be due to their relatively strong

perceived stigma and feelings of familial disgrace to outsiders whom they perceive to be difficult in understanding their family situations (Bae and Kung, 2000). Literature reviews on family intervention for people with schizophrenia also recommend that an intensive face-to-face family therapy may not be cost-effective and clinically efficacious due to limited manpower (trained therapists) and resources (Chien and Chan, 2013, Dixon et al., 2001).

Furthermore, most family interventions using self-help or peer support formats mainly established and studied in Western countries may not be able to applied to Chinese or Asian people who have a strong family-oriented and collectivism culture (Chien and Chan, 2013, Chien and Norman, 2009). With positive effects of self-help programmes for primary carers of people with chronic physical/mental health problems found in Western countries (D’Zurilla and Nezu, 2007, Jorm et al., 2002, World Health Organisation, 2002), a design and evaluation of a user-centred and self-help problem-solving-based family intervention in recent-onset psychosis would be important and essential to family caregivers and their patients in Chinese/Asian populations.

1.1. Aim and hypotheses of the study

This randomised controlled trial was to test the effects of a self-help problem-solving-based bibliotherapy (SPBB) for Chinese family caregivers of patients with recent-onset psychosis on both family caregiver and patient outcomes over a 6-month follow-up, compared to those who received usual family support services only. Primary outcomes of this study included caregivers’ burden and caregiving experiences; and the secondary outcomes consisted of patients’ psychotic symptoms, functioning and rehospitalisation rate, and caregivers’ social problem-solving skills. The study hypotheses were that the families in the SPBB would indicate significantly greater reductions in their caregivers’ burden and patients’ psychotic symptoms and re-hospitalisations, and improvements in these caregivers’

experiences of care provision, social problem-solving skills and their patients' functioning over the 6-month follow-up, than those with usual family support service only.

2. Methods

This was a randomised controlled trial with repeated-measures, parallel-group design, which was carried out at one psychiatric outpatient clinic in Hong Kong (May 2014 to June 2016; recruitment period: June-September 2014; 6-month follow-up: November 2014 - July 2015). While this controlled trial would have four post-tests over 24 months follow-up (refer to the clinical trial register of ClinicalTrials.gov, NCT02391649, at <https://register.clinicaltrials.gov>), this paper reported its results over the first 6 months post-intervention. With significant positive results available, the programme would be considered part of the usual psychiatric care provided by the clinic. The procedure of this controlled trial based on the revised CONSORT statement (Schulz et al., 2010) is presented in *Figure 1*.

Insert Figure 1 here

2.1. Recruitment

Patients diagnosed with recent-onset psychosis (i.e., ≤ 6 months of onset) were selected randomly by one researcher (WTC) from a patient list of Early Psychosis Services at one regional outpatient clinic in the New Territories of Hong Kong. The outpatient clinic served for 20% (500,000) of Hong Kong population. There were 850 patients with recent-onset psychosis identified from the clinic records (11% of the patient population) at recruitment; after initial screening from patient records, 400 of them met the below study criteria. The randomisation procedure was guided by the standardised protocol of the National Health and Medical Research Council (NHMRC) Clinical Trials Centre (2013). The eligible patients was arranged and listed in terms of their surnames in alphabetical order. According to our experience of family intervention studies, there could be 10-15% of approached patients disagreed to participate (Chien et al., 2006, Chien and Chan, 2013). Therefore, 135 eligible

patients were randomly selected from the patient list, using the computer-generated random numbers generated by an independent statistician to avoid selection bias (NHMRC Clinical Trials Centre, 2013). When approached by the first author, 15 patients refused to participate. Finally, 116 of 131 invited patients consented to participate after the researcher fully explained the study purpose and procedure. The response rate was 89%. With the patients' written consent for participation, the first author contacted and invited one main family carer nominated by the patient for participation in this study via telephone calls, or when they accompanied with the patient to attend the outpatient follow-up in the clinic.

The inclusion criteria of participants were family caregivers who were: (a) ≥ 18 years old and able to communicate in Chinese/Cantonese; and (b) primary carers, living with and providing most daily care for the patient with a clinical diagnosis of recent-onset psychosis as recommended by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Text-Revised Edition [DSM-IV-TR] (American Psychiatric Association, 2000). The patients included were those who were: (a) patients with recent-onset psychosis who did not have any co-morbidity of other mental disorders; (b) the first contact to mental health services; and (c) not participating in any family/psychosocial intervention. Family caregivers were excluded if they themselves diagnosed with mental disorders, and/or they were also the main care provider of another relative with a chronic physical/mental illness. In addition, the patients who had unstable mental state or would be re-hospitalised prior to study group allocation were also excluded.

Following the baseline measurement during their visit to the clinic, the caregivers were assigned into one of the two study groups in sequence order of the patients' outpatient follow-up dates using another set of computer-generated random numbers prepared by the statistician. Finally, 58 pairs of family caregivers and patients were randomly allocated into each of the two study groups; whereas, the participant list was safely stored in a locked

cabinet by the research assistant and concealed to the researchers, clinic staff and outcome assessor during data collection. In addition to the non-accessible participant list, the concealment of study participation and/or intervention assignment was maintained by a few means (NHMRC Clinical Trials Centre, 2013): (a) the participants were asked not to discuss the study or their intervention with the clinic staff; (b) a trained part-time research assistant who was concealed from the intervention assignment conducted all post-tests; and (c) one researcher not involved in subject recruitment and intervention implementation entered all study data.

2.2. Sample size estimation

With consideration to the study hypotheses and outcomes, the sample size was calculated on the basis of two clinical trials of family intervention, including one for Chinese psychotic patients using psycho-educational approach (Chien and Bressington, 2015) and another one for Australians with first-episode psychosis using bibliotherapy (McCann et al., 2013). The effect sizes on family burden/distress were found to be 0.68 and 0.52, and re-hospitalisation rate (days of re-admissions) were 0.60 and 0.50, in the two studies. To achieve an 80% of study power (two-sided, $p < 0.05$) and an expected 15% of attrition rate, it was estimated that 58 families per group would be adequate to detect a moderate effect size=0.50, which was the smallest one of the above two outcomes. Whereas, there would be a difference of mean score changes in family burden for 1.5 units/points (standard deviation=2.7), or in re-hospitalisation rate for 5 days of hospital-stay during the past three months (standard deviation=9.0). We adopted this relatively low attrition rate due to our previous research experiences in family-based intervention (Chien et al., 2006, Chien and Chan, 2013); regular reviews and telephone follow-up the SPBB participants by a trained research assistant; and encouragement of all participants to continue participation in the study provided by the clinic staff.

2.3. Measures

The family caregivers were invited by the trained research assistant who was blind to intervention allocation to complete a set of outcome measures at recruitment and two post-tests, including Family Burden Interview Schedule (FBIS), Experience of Caregiving Inventory (ECI) and Social Problem Solving Inventory, Revised: Short version (SPSI-R:S). The research assistant also administered the Specific Level of Functioning Scale (SLOF) to the patients. The Chinese versions of these scales used in this study were tested/validated with satisfactory reliability and validity among Chinese families in psychotic disorders (Chien and Chan, 2013, Lau and Pang, 2007, Siu and Shek, 2005). During OPC follow-up, the attending psychiatrist assessed the patients' psychotic symptoms with the Positive and Negative Syndrome Scale, PANSS (Kay, Fiszbein and Opler, 1987). The research assistant also checked the number and duration of patients' re-hospitalisations and total number of patients per group hospitalised over the previous six months, as well as the dosages of psychotropic medication, from the patients' outpatient clinic records.

Caregivers and their patients were also asked by the research assistant to provide their socio-demographic data, for example, their age, education level, duration of mental illness, and current treatment at recruitment. Types and dosages of antipsychotic medications were examined from the treatment sheets of patients; whereas, these dosages of psychotropic medication were transformed into their haloperidol equivalents for comparisons (Bezchlibnyk-Butler, Jeffries and Virani, 2007, Chien and Chan, 2013).

The 25-item FBIS was used to measure the level of carers' burden of care provision to a family member suffered from schizophrenia at home (Pai and Kapur, 1981). Items of the Chinese version of FBIS were rated on a three-point Likert scale (from 0-'no burden' to 2-'severe burden'). The Chinese version demonstrated good internal consistency (Cronbach's

$\alpha=0.78-0.88$) and adequate test-retest response stability (intra-class correlation= $0.83-0.92$) in families of people with psychotic disorders (Chien and Norman, 2004).

The 66-item ECI based on transactional model of stress-appraisal-coping (Szmukler et al., 1996) was used to measure positive (e.g., improved family relationships) and negative (e.g., stigma and problems with service utilisation) experiences of caregiving to a relative with mental illness. A 5-point Likert scale (0-‘never’ to 4-‘nearly always’) was used for item ratings; whereas, a higher total score would indicate a more negative appraisal of caregiving experiences. The Chinese version used in this study demonstrated very satisfactory content validity, and acceptable internal consistency (Cronbach’s $\alpha=0.80$), in Chinese families who were taking care of a relative with serious mental illness (Lau and Pang, 2007).

The 25-item SPSI-R:S was used to assess an individual’s ability of social problem-solving. This scale contained two domains, including problem-solving style (e.g., rational problem-solving and impulsivity) and orientation (positive and negative), which was scored on a 5-point Likert scale: 0-‘not-at-all true’ to 4-‘extremely true’ of me. It indicated acceptable internal consistency (Cronbach’s $\alpha=0.68-0.81$), and concurrent validity with a few coping scales, in Hong Kong Chinese adults (Siu and Shek, 2005).

The 30-item PANSS assessed the severity of psychotic symptoms, which was scored on an 8-point Likert scale: 0-‘absent to’ 7-‘extreme’. The PANSS indicated a high concurrent validity with psychiatric symptom rating scales and satisfactory test-retest reliability (i.e., their intra-class correlations were between 0.85 and 0.90), as well as good internal consistency (Cronbach’s $\alpha=0.88-0.91$) in psychotic patients (Bell et al., 1992).

The 43-item SLOF was scored on a 5-point Likert scale (i.e., 1-‘totally dependent’ to 5-‘highly self-sufficient’) in terms of three domains, including self-care or maintenance, social functions and independent community living skills (Schneider and Struening, 1983). Very

satisfactory internal consistency (Cronbach's $\alpha=0.88-0.96$) and high content validity among psychotic patients were reported in the Chinese version used in this study (Chien et al., 2006).

2.4. Treatment

Family caregivers (n=58) in the treatment group undertook a 5-month guided self-help, problem-solving based bibliotherapy (SPBB), in addition to routine psychiatric care. Each caregiver completed a Chinese problem-solving-based self-reading manual for carers in first-episode psychosis (McCann et al., 2013) translated and validated by the research team. The bibliotherapy manual adopted the problem-solving approach to illness management (D'Zurilla and Nezu, 2007), which was 'a self-directed cognitive-behavioural process by which a person (carer) attempts to identify and discover effective/adaptive solutions for specific problems encountered in everyday living' (p.11) concerning his/her caregiving to a relative with chronic illness. It involved guided learning by reading the written information and references (i.e., 8-10 hours to complete rating each module), enabling the individual primary caregivers in this study to 'step-by-step' solve their problems in taking care of their relative with recent-onset psychosis. The SPBB consisted of five modules: Module 1, 'Caring for caregiver's own well-being'; Module 2, 'Getting the best out of family support services'; Module 3, 'Promoting well-being of your family member with early psychosis'; Module 4, 'Dealing with the impacts of the illness on psychosocial health'; and Module 5, 'Dealing with impacts on family and physical health' (i.e., the outline of this manual in Table 1). By completing the case studies and exercises in the five modules, each caregiver was facilitated to develop a positive attitude and rehearse appropriate behaviours towards caregiving, identify his/her major problems in caregiving situations, predict implications of each alternative, and finally, try out the solution in daily lives and monitor if it worked.

Insert Table 1 here

Whilst individual caregivers read, thought and practised through the five modules of the SPBB independently across approximately 20 weeks, the first and second researchers conducted two introductory and brief education sessions (2 hours each during the first and second week) about the illness and community care, and three review sessions (1.5-hour sessions in the sixth, twelfth and twentieth weeks). The caregivers were encouraged to complete one module per month and their progress of module completion and learning of problem-solving skills in caregiving were discussed in the three scheduled review sessions. Specific Chinese cultural considerations were added in the manual and/or review sessions, especially on open disclosure/discussion about intense negative feelings and family needs, social stigma towards mental illness, nurturing interdependent/collective behaviours on caregiving among relatives, and more emphasis on practical helps or aids for patient and family affairs (Chien and Norman, 2008, Chien and Thompson, 2014). Treatment adherence to the SPBB was monitored with weekly telephone calls by a trained part-time research assistant. The research assistant asked each of the caregivers a set of standardized questions concerning their understanding about those module contents, and any difficulties encountered. The research assistant also assessed their levels of intervention fidelity (i.e., the completion of/adherence to the modules) with a checklist. The checklist consisted of 40 items (8 items per module), covering the main contents for problem-solving and self-learning in caregiving. For example, the caregiver becomes aware a few important family problems/needs and identify a few practical ways to meet each other's needs in Module 1; the caregiver can recognise a carer's contributions to patient's treatment/recovery and being alert for early signs of relapse in Module 3; and the caregiver can work out and practise how to reduce/solve problems related to weight gain with the patient in Module 5. In addition, the caregivers could seek clarifications about the materials covered in their readings and learning of the modules during the telephone calls or review sessions.

A panel of six experts (psychiatrists, rehabilitation nurses and psychologists) assessed and rated the relevance, appropriateness and clarity on the manual contents to family caregiving and community mental healthcare, the case examples and exercises used in each module and with prior consent from the caregivers, evaluated their progress of module completion by working through or reviewing four randomly selected sets of three audio-recorded review sessions and telephone conversations. Overall, the relevance and appropriateness of the content and exercises used in the manual, questioning in the phones, and items covered in the review sessions were rated very satisfactory and excellent (i.e., 93-99% relevance and appropriateness).

Caregivers in usual care (n=58; as well as the SPBB participants) were provided with the usual or standard psychiatric outpatient care and family support service, comprising medical consultations and psychiatric treatment for patients by a psychiatrist (over every 4 to 8 weeks), family education sessions (two to three, 2-hour) about mental illness and its treatments by mental health nurses, social benefit and welfare and individual or family counselling services by medical social workers, and social skills training by mental health nurses or occupational therapists, as needed. The usual family support group also received a small information booklet about looking after caregiver's well-being by which the Hawthorne effect that occurred with the SPBB could be compensated.

2.5. Data collection procedure

With written consents received from participants, the research assistant administered the baseline measurements (Time 1) with the pairs of family participants (caregivers and patients) in a quiet interview of the clinic and after that, these pairs were randomly allocated into the study groups by one part-time research assistant. In the telephone calls during the intervention period, the part-time research assistant assessed the levels of intervention fidelity among the caregivers using a checklist of 40 module items. During the outpatient follow-up or

home visit, the research assistant again administered the outcome measures (for three post-tests) with the caregivers and their patients at 1-week (Time 2) and 6-month (Time 3) after the completion of the interventions. In addition, the research assistant checked about the patients' re-hospitalisations (number and days of hospital-stay per month), total number being hospitalised in each study group, and psychotropic medications in the previous six months from the clinic records.

2.6. Ethical considerations

Ethical and access approvals of the study was granted by the two outpatient clinics under study, and the Human Research Ethics Sub-committee of The Hong Kong Polytechnic University. Informed written consent was sought from both caregivers and patients to participate on a voluntary basis before random selection of the participants; and each participant was allowed to clarify questions about the study purpose and procedures. Confidentiality on personal identity and information collected and their right of withdrawal (at anytime) from the study were assured.

2.7. Statistical analyses

The IBM's SPSS, version 21 was used to code, check and analyse all quantitative data from the caregivers and patients in this study. Based on intention-to-treat principle, all outcome data could be analysed by maintaining the advantages of random allocation as those participants who withdrew/non-adhered in the interventions and/or follow-ups were still included in the final data analysis (Tabachnick and Fidell, 2001). Similarities of the characteristics between two study groups on their socio-demographic and baseline outcome variables was checked with independent sample t (2-tailed) or Chi-square test; any co-variants for the analyses of the treatment effects could be identified. Without any violation of assumptions on multivariate normality, linearity, outliers, and equality of variance-covariance (Stevens, 2002), a mixed-model multivariate analysis of variance (MANOVA) test was

conducted to determine the interaction (Group x Time) treatment effects of the interventions, and the univariate between-group effects across time on the outcome variables [FBIS, ECI, SPSI-R:S, SLOF, PANSS, dosage of psychiatric medication, and number and length of re-hospitalisations]. If the between-group effects were found significant on the outcome measures, Helmert's contrast code tests were then used to identify where the significant mean score difference(s) on each of the outcome(s) was/were located (Tabachnick and Fidell, 2001). The total number of patients admitted in mental hospital over the past six months was compared between groups at baseline and two post-tests using Mann-Whitney U test. Levels of significance for all statistics used in this study were set at $p < 0.05$, except the ANOVA tests for univariate between-group effects across time set at 0.006 (using the Bonferroni's adjustment suggested by Stevens, 2002).

3. Results

3.1. Characteristics of study participants

One hundred and eleven of the 116 randomly selected families (96%) completed the interventions and follow-up. Two in both the SPBB and usual family support group withdrew or were lost to contact at the first post-test (Time 2) and thus were not being included in the data analysis (Figure 1). While one caregiver discontinued their participation (and the above two withdrew) from the SPBB, 55 (95%) completed at least 4 of 5 modules of the manual and 2 of 3 review sessions (i.e., >75% of the SPBB). Reasons for withdrawal or discontinuation from study participation in the SPBB mainly included: inadequate time to read the material or participate in the intervention ($n=2$), very poor mental state of patient ($n=1$), and not having any interest or desire to continue their participation ($n=2$). The levels of intervention (SPBB) fidelity among the caregivers ranged from 87.5% to 95.2% with an average of 92.1%, indicating a satisfactory adherence to the SPBB manual.

A summary of the socio-demographic characteristics of the family dyads/participants (n=58 in each group) is shown in Table 2. The mean age of the family caregivers was 38 years (M= 36.7 and SD= 8.3 in SPBB; M= 39.6 and SD= 8.0 in usual family support alone), with a range of 20-53 years. Two-thirds of them were female (63.8% and 65.5%), and parent or spouse (65.0% and 63%).

Insert Table 2

The patients' mean age was around 25 years (SD=8.5, range 18-39). More than half (55.2% and 56.9%) of them were male and more than 82% received a low to medium dosages of antipsychotic medication (range of haloperidol equivalents were 7.2-11.9 mg/day, as suggested by Bezchlibnyk-Butler et al., 2007). Over 80% of them (82.8% and 84.5%) were on oral medication only, mainly including atypical, typical or blended antipsychotics (82.8% in both groups). The duration of illness for the patients was in average of 3.8 months (SD=2.8, range 1-6 months).

All socio-demographic characteristics did not differ between the two study groups ($p > 0.12$) and no significant correlations (i.e., Spearman's $r < 0.11$) were found between their demographic and outcome variables at baseline. Hence, there were not any covariate effects detected from these study variables.

3.2. Treatment effects

The mean scores of all caregiver and patient outcomes have indicated no significant differences between the SPBB and family support service alone group at baseline ($p > 0.18$). There were only few missing data, which were two outcome variable scores in the two study groups at the post-tests. Based on an intention-to-treat principle, the previous data were brought forward to fill up the missing values (Tabachnick and Fidell, 2001); however, there were very minimal differences found in the results. The MANOVA test results showed that when considering all of the outcome variables together, a statistically significant between-group difference [$F(6,110) = 6.70$, $p = 0.0008$; Wilks' Lambda (Λ) = 0.89; partial eta-squared

(η^2)= 0.49, indicating a large effect size] was found. *Table 3* shows the mean values (standard deviations) of the study outcomes and their independent univariate F values between groups across four measurements. Statistically significant interaction (Group x Time) treatment effects of the SPBB were found, indicating significant greater improvements (and large effect sizes of 0.51-0.82) in caregivers' ECI score [F(1,110)=6.88, p=0.0004] and FBIS score [F(1,110)= 6.21, p= 0.005), as well as in patients' SLOF score [F(1,110)= 7.01, p= 0.0005], PANSS score [F(1,110)= 6.25, p= 0.003], duration of re-hospitalisations [F(1,110)= 5.71, p=0.005].

Insert Table 3 here

The mean score differences (from the baseline values) at the two post-tests were found to be statistically significant differences between the SPBB and usual family support group on the following outcome variables:

- Family caregiving experiences (ECI) and burden (FBIS) mean scores of the SPBB improved significantly at Time 2 (mean difference= 11.9 and 2.6, p= 0.001 and 0.0001, respectively) and Time 3 (mean difference= 27.4 and 7.6, p= 0.0004 and 0.001, respectively), compared to those received usual family support services alone.
- Patient functioning (SLOF score) of the SPBB increased (mean difference= 13.8 and 34.8, p= 0.001 and 0.0002) and the severity of their psychotic symptoms (PANSS score) reduced significantly (mean difference= 12.7 and 47.0, p= 0.0003 and 0.0002, respectively) at Times 2 and 3, compared to usual care alone.
- Length of re-hospitalisations for the patients in the SPBB significantly reduced at Times 2 and 3 (mean difference= 6.8 and 10.0, p= 0.002 and 0.0008, respectively), compared to usual care alone.

In addition, the SPBB group indicated a significant greater decrease in total number of patients who had been hospitalised over the past six months at two post-tests [Time 2: 14

(25%) versus 23 (41%); Time 3: 8 (14%) versus 19 or (34%)], compared to those with the usual family support service alone ($p=0.004$ and 0.0008 ; see Table 3). However over the 6-month follow-up, the mean scores on the above study outcomes were found no significant difference between the SPBB subgroups, in terms of patients' symptom remission (all PANSS item scores <2 over the past 3 months) and availability of other caregiver(s) ($p=0.15-0.38$).

4. Discussion and Conclusion

4.1. Discussion

This is the first controlled trial to test the effectiveness of self-directed, manual-reading programme (SPBB) based on self-reading and guided problem-solving approach for family caregivers to learn/practise family support and care for patients with recent-onset psychosis. The findings are very encouraging and positive for the use of mainly self-help and manual-reading for family caregivers to learn and practice their care provision to a relative with psychosis and solving its related problems encountered. As the result, the 5-month SPBB can improve caregivers' experiences and burden of care and a few caregivers' and patients' psychosocial health at 6-month follow-up. This provides support for the application of bibliotherapy as an effective approach to family intervention in facilitating and empowering family caregivers to care for the patients in early-intervention psychosis services. Indeed, these findings were more positive and long-lasting (over 6 months) than those found in another bibliotherapy programme conducted with 16-week follow-up in two early psychosis services in Melbourne, Australia (McCann et al., 2013). While McCann et al.'s clinical trial of bibliotherapy for family caregivers of young psychotic patients indicated only a few significant improvements in negative caregiving experience and distress at 6-week follow-up, the results in this study indicate more significant substantive improvements in wider varieties

of caregiver (i.e., family burden and caregiving appraisals and experiences) and patient (psychosocial functioning, psychotic symptoms and re-hospitalisation rates) outcomes at 6-month after completion of the SPBB, compared to those receiving usual family care only.

Recent systematic reviews (Addington et al., 2001, Gylmn et al., 2006, Pharoah et al., 2010, Onwumere et al., 2011) on family intervention studies in recent-onset and later stages of psychosis suggest that most current approaches to family intervention have demonstrated inconsistent and low to moderate effects on family caregivers' general health and well-being, as well as their functioning, in a longer period of follow-up, such as over one year. However, this study has demonstrated that the SPBB for caregivers of people with recent-onset psychosis can produce more substantive and wider aspects of benefits on both patient and caregiver health outcomes over 6 months post-intervention. Given such half-year significant benefits on these families' psychosocial health conditions found in this trial, the self-help, problem-solving-based manual-reading intervention (so called 'bibliotherapy') is suggested to be an effective family intervention in recent-onset psychosis, in addition to the provision of usual community mental healthcare services.

Self-directed, problem-solving strategies have been increasingly used or integrated into interventional studies as part of the psychosocial skills training for family caregivers or patients in an early stage of serious mental disorders, for example, schizophrenia, substance misuse and other psychotic disorders (Grawe et al., 2006, Gylmn et al., 2006, Dixon et al., 2011). Nevertheless, the effectiveness of self-help problem-solving approach to family intervention in recent-onset psychosis, or inclusion of this bibliotherapy programme, in community mental health care has not yet been studied; and thus their contributions to these families' health outcomes are uncertain (Onwumere et al., 2011). Therefore, the findings of this controlled trial lend support for establishing a self-directed, problem-solving programme for these psychotic patients, as this programme has demonstrated very positive benefits to the

perceived burden or distress and positive appraisals of caregiving experiences among carers and importantly, to the patients' psychotic symptoms and re-hospitalisations.

Notwithstanding some positive effects of family psycho-education and behavioural management programmes, this self-help therapy in book form (bibliotherapy) with very positive benefits shown in this study, and not requiring a family therapist with extensive training or costly and intensive resources, can be very likely adopted and increasing its accessibility and penetration in the current community mental healthcare services. This bibliotherapy can be conducted and managed by caregivers themselves with only minimal face-to-face education and guidance from health professionals, although this approach can sometimes function best in combination with other approaches to psychosocial intervention (Campbell and Smith, 2003). The self-reading manual itself is ready to access or reach and provides readers (caregivers) an opportunity to study and revise the reading material at their convenience of time and place as needed, without spending much time to attend the therapy sessions. It can also empower caregivers to be engaged in their self-care and more able to focus on the specific needs of their families (McCann et al., 2013, Petrakis et al., 2013). Nevertheless, this controlled trial of bibliotherapy is one of very little research in family caregivers of people with recent-onset psychosis, and has strengthened its wider application from people with depression and anxiety to those with early psychosis (Fanner and Urquhart, 2008, McKenna et al., 2010, McCann et al., 2013).

The findings of this study also indicated that the psychotic symptoms (PANSS score) of the patients in the SPBB reduced steadily over the 6-month follow-up. These findings could reflect a strong motivation and inspiration of those family caregivers in the SPBB towards better patient care and outcomes in the community-based rehabilitation and mental healthcare service, as suggested by other family intervention studies in first-episode psychosis (Grawe et al., 2006, Petrakis et al., 2013). In line with the symptom reduction, the patients' risk and

frequency of re-hospitalisations in the SPBB participants were also significantly reduced (i.e., 64% and 59% reduction, respectively, at 6 months post-intervention). The findings can also be explained by the benefit of the SPBB in increasing caregivers' knowledge about the illness and problem-solving skills, which could lead to their better coping with the newly adopted caring role and making better use of community mental health care services as preferred (Craig et al., 2004, Guo et al., 2010). Consequently, these caregivers could better facilitate their patients to manage the mental illness and its symptoms. In addition, the module/intervention completion rate by the caregivers was very high (93%); whereas, the attrition rate was very low (5%), in contrast with other family intervention studies in early psychosis (Grawe et al., 2006, Onwumere et al., 2011). These favourable results may be attributed by the problem-solving skills training, the self-help, user-friendly and easy reading material, a few bolstering review sessions, the time flexibility of completing the five modules, and/or any of their combined effects. Nevertheless, the SPBB was less resource intensive and lengthy than other psychosocial interventions in recent-onset psychosis [e.g., Glesson et al.'s (2013) 7-month Cognitive-Behavioural Therapy based relapse prevention programme with >10 face-to-face sessions) and thus easier and feasible to be implemented in community mental health care settings.

Contrasting with the common belief that there should be a long duration (e.g., 9-12 months) and/or intensive individual/group format in family intervention, this controlled trial has adopted a highly accessible and structured manual-reading, self-learning material to the readers (caregivers), a strong family partnership in self-care, and a reasonable 5-month programme. Indeed, significant positive results/benefits on both caregivers' experiences and burden of care and their patients' mental state and re-hospitalisations were reported and sustained over 6-month follow-up. Only limited clinical trials (Addington et al., 2005, Gleeson et al., 2010, McCann et al., 2011) reported that manual-guided self-learning

programme could only provide short-term (4 weeks to 3 months) effects on caregiving experience and psychological distress; however, this SPBB demonstrated longer term and more significant benefits in a variety of caregiver and patient outcomes to the first-time caregivers of people with recent-onset psychosis. In addition, this study ensured high quality and standard of a randomised controlled trial such as clear procedures of subject recruitment and randomisation, blinding of outcome assessor, researchers and clinical staff during recruitment and data collection, and monitoring of the fidelity of the SPBB through regular reviews with caregivers and discussion among the research team about the process/progress of self-reading, understanding about the reading material and self-directed practices, with reference to the audio-taped review sessions (and telephone conversations).

The exceptional low attrition rates of family caregivers in this study, especially the SPBB participants, are much more desirable than other family intervention studies in psychotic disorders. In addition to the expected benefits induced by the problem-solving-based self-help programme with a brief, convenient and easy-to-read manual supported by regular review sessions and telephone calls, there may be three possible explanations. First, first-time family caregivers might have viewed that although the researchers who were not a clinic staff had informed them the study participation was voluntary, they were mandatory to participate/complete the intervention. Second, the family carers had a few specific characteristics such as highly motivated participants with their income and education higher than the general population of Hong Kong and a Chinese/Asian culture of respect and trust for someone perceived to be in authority such as therapists/professionals (Chien and Norman, 2009). The strong enthusiasms among the caregivers towards oneself, patient and family care could contribute to their highly desirable completion rates of the SPBB. Finally, there are very few tailored and user-friendly family support services or interventions have been

provided to Hong Kong caregivers of patients with recent-onset psychosis (Addington et al., 2001; Chien et al., 2006; Chien and Norman, 2009).

4.1.1. Limitations and future research

There are three main limitations that may affect the validity and generalisation of the findings. First of all, the participants (family dyads) in this study were recruited from one psychiatric outpatient clinic and had the onset of recent-onset psychosis for ≤ 6 months. Despite randomisation of the participants, the sample was somewhat selective (e.g., volunteered and middle-class families) and the caregivers could be highly motivated and have an optimistic view about patient recovery, as well as family well-being (Grawe et al., 2006, Chien and Norman, 2009). This might result in the high completion and low attrition rates of the caregivers in this study. The random selected family dyads (patient and main family caregiver) were found to be similar to those non-participants ($n=284$) in term of their socio-demographic and clinical characteristics (using Chi-square test, $p>0.12$), thus indicating representative to the population of recent-onset psychosis in one geographical region of Hong Kong. Nevertheless, the generalisation of the findings to the whole Hong Kong patient population or patients with recent-onset psychosis in other countries is uncertain, thereby needing further investigation in these families with diverse backgrounds.

Second, the caregivers' reading progress and completion of the modules have been monitored, but their understanding of the module content and problem-solving practices for individual family concerns/problems might not be easy to standardise or address as what could be achieved with a face-to-face educational intervention (Cuijpers et al., 2010). Third, the level of engagement in reading, information seeking and review sessions and interactions with other caregivers (or family members), and the research team, may have contributed significant psychosocial effects on the participants (caregivers) in this study (Chien and

Chan, 2013), which were not investigated in this trial. The single or combined effect of main components of the manual-guided SPBB programme could not be confirmed in this study; further research on its therapeutic components/mechanisms is therefore recommended.

Last, the controlled trial was single-blind design with a medium term follow-up and no active comparison group, thus inducing Hawthorne effect from the participants who undertook the intervention and unable to claim the superiority and long term (e.g., >1 year) effects of the SPBB in comparison with other psychosocial or self-help interventions in recent-onset psychosis. In addition, we did not assess how successful the means for the concealment of study participation and/or intervention assignment was. For instance, the participants might discuss the study or their intervention with the clinic staff. Therefore, it should be noted that any unsuccessful allocation concealment in this trial might confound or exaggerate the treatment effects, as suggested by the CONSORT group (Schulz et al., 2010).

4.2. Conclusion

This controlled trial of a manual-guided, problem-solving-based self-learning programme provides evidence on medium-term (6 months) benefits for family caregivers of people with recent-onset psychosis on both caregivers' and patients' psychosocial health conditions, when compared to those in usual family support services only. This trial supports the view that manual-guided self-learning programme can be effective in community care to help not only mostly Western people with affective and learning disorders within various healthcare or school contexts, but also the first-time caregivers in an early stage of psychosis in Chinese populations. The results has also indicated more positive and longer-term benefits than those of a pilot controlled trial in Australia (McCann et al., 2013) using a similar family bibliotherapy manual in first-episode psychosis with 16-week follow-up (McCann et al., 2013). It is crucial to find out that both the family caregivers and their patients have got significant improvements in their psychosocial and mental health conditions, as well as

positive experiences in the process of caregiving over the 6 months follow-up period. These findings can support a need for further research about this self-learning (bibliotherapy) intervention for family caregivers with diverse socio-demographic, ethnic and cultural backgrounds in Chinese/Asian countries, and/or for patients with longer duration of illness and/or co-morbidities and disturbances of other physical/mental disorders.

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Table 1. Outline of the content of self-help problem-solving based bibliotherapy

Stage	Goals/Objectives	Main content	Length of each stage ^a
Orientation (engagement)	Introduction of the programme and understanding of the illness/ treatment	<ul style="list-style-type: none"> • Orientation to the SPBB; establishing therapeutic relationship and goal setting • Accepting roles and responsibilities of a caregiver and manual user • Understanding the illness and its community support, importance of family caregiving and coping with such demands • Discuss difficulties in caregiving and family life and impacts/burden to family • Identifying the needs for patient's psychosocial support and rehabilitation in the community 	2 sessions (2-hour sessions in the first and second week)
Caregiver's well-being and coping skills	Working through caregiver's emotions and current coping methods and exploring the most effective ways of coping; managing the impacts of the illness to caregiving and family life	<p>Module 1: Caring for the caregiver</p> <ul style="list-style-type: none"> • Self-reflecting on emotions and wellness and identifying perceived burden of care and distress • Learning and practicing optimistic, adaptive problem-solving approach in caregiving <p>Module 2: Getting the best use of family support services</p> <ul style="list-style-type: none"> • Understanding caregiver's rights, confidentiality and roles, and seeking social support • Communicating and establishing relationships effectively with patients, family members and professionals; Encouraging and facilitating help seeking • Practicing the learned approach to and steps 	Completing one module per month

of problem-solving

Module 3: Promoting well-being of family member with *recent-onset psychosis*

- Recognising carer's contributions to patient's treatment/recovery and being alert for early signs of relapse
- Promoting mental health and well-being of patient and other family members with emotional support and practical assistance
- Understanding relapse prevention, medication adherence and stress management
- Reinforcing rehearsals and practices of problem-solving skills in daily life

Module 4: Dealing with impacts of the illness on psychosocial health

- Exploring ways to respond to suicidal/self-harm ideas and negative emotions in family care
- Reflecting own attitude towards caregiving and conflicts with patient and other family members
- Learning self-care, relaxation, alertness of danger and behavioural changes, and seeking helps, as needed

Module 5: Dealing with impacts of the illness on family's physical health and well-being

- Assessing and reducing social withdrawal, high risk behaviours (e.g., aggression and harms) and sleep problems; assisting patient to manage psychotic symptoms and behaviours
-

		<ul style="list-style-type: none"> • Managing excessive weight change, patient's non-adherence to treatment/education, and substance misuse • Practicing effective communication and motivational interviewing skills in family care 	
Review and plan for future	Reflection of learning experiences in caregiving and seeking any improvements	<ul style="list-style-type: none"> • Reviewing self-care, coping strategies and practices of problem-solving in family situations over the past few months • Evaluation of self-motivation (-care), manual-reading and caring experience, problem-solving skills, and goal achievements • Discussing the continuity of care after intervention, personal and community resources, and community service utilisation • Making a realistic future plan 	3 sessions (1.5-hour sessions in the sixth, eleventh and twelfth weeks)

SPBB= Self-help Problem-solving Based Bibliotherapy.

^a The bibliotherapy comprised five modules of guided self-help, problem-solving manual, together with two orientation and three face-to-face review sessions, completed within five months.

Table 2. Characteristics of caregivers and patients with recent-onset psychosis (N=116)

Characteristics	SPBB (n= 58) ^a	Usual family support (n= 58) ^a	Unpaired t or Chi-square test value ^b	P
<u>Family Caregivers</u>				
Gender				
Female	37(63.8)	38(65.5)	1.30	0.19
Male	21(36.2)	20(34.5)		
Age (years)				
	M=36.7, SD=8.3	M=39.6, SD=8.0	2.35	0.12
20-29	12(20.6)	9(15.5)		
30-39	23(39.7)	23(39.7)		
40-49	15(25.9)	17(29.3)		
50 or above	8(13.8)	9(15.5)		
Education level				
Primary school or below	9(15.5)	10(17.3)	1.59	0.27
Secondary school	38(65.5)	39(67.2)		
University or above	11(19.0)	9(15.5)		
Relationship with patient				
Child	10(17.3)	10(17.3)	1.70	0.24
Parent	20(34.4)	18(31.0)		
Spouse	18(31.0)	19(32.7)		
Others (e.g. sibling and grandparent)	10(17.3)	11(19.0)		
Monthly household income (HK\$)^c				
	M=15,680, SD=2,933	M=16,920, SD=3,178	2.40	0.11
5,000 – 10,000	9(15.5)	8(13.8)		
10,001 – 15,000	20(34.5)	21(36.2)		
15,001 – 25,000	21(36.2)	20(34.5)		
25,001 – 35,000	8(13.8)	9(15.5)		

Patients				
Gender				
Female	26(44.8)	25(43.1)	1.13	0.30
Male	32(55.2)	33(56.9)		
Age (years)				
	M=24.8, SD=8.2	M=25.6, SD=8.9	1.09	0.37
18-25	29(50.0)	29(50.0)		
26-30	21(36.2)	22(37.9)		
31-40	8(13.8)	7(12.1)		
Duration of illness (months)				
			1.10	0.36
1 – 2	17(29.3)	18(31.0)		
3 – 4	26(44.8)	27(46.6)		
5 – 6	15(25.9)	13(22.4)		
Types of psychotropic medication				
			1.28	0.28
Atypical antipsychotic	20(34.5)	19(32.8)		
Typical antipsychotic	19(32.8)	19(32.8)		
Anti-depressant	7(12.1)	6(10.3)		
Anxiolytic	3(5.2)	4(6.9)		
Blended mode ^d	9(15.4)	10(17.2)		
Dosage of medication^e				
			1.98	0.18
High	10(17.2)	9(15.5)		
Medium	20(34.5)	25(43.1)		
Low	28(48.3)	24(41.4)		

SPBB= Self-help Problem-solving Based Bibliotherapy.

^a denotes frequency (f %) or M (mean) and SD (standard deviation).

^b Independent sample t-test (df=1, two-tailed) or Chi-square Good-of-fit test was used to compare the socio-demographic variables of families between two study groups.

^c US\$1 = HK\$7.8.

^d Blended mode of medication mainly included combined use of atypical and typical antipsychotics, or antipsychotic and anti-depressant.

° Dosage levels of antipsychotic medication were compared with the average dosage of medication taken by patients with schizophrenia in Haloperidol equivalent mean values (Bezchlibnyk-Butler, Jeffries and Virani, 2007).

Table 3. Outcome measure scores at four times of measurement and results of MANOVA (Group x Time) test (N = 116)

Instrument	SPBB (n = 56)									Usual family support (n = 56)									F (1,110)
	Time 1			Time 2			Time 3			Time 1			Time 2			Time 3			
	M	SD	Range	M	SD	Range	M	SD	Range	M	SD	Range	M	SD	Range	M	SD	Range	
ECI ^a (0-204) ^b	130.8	19.0	106-152	118.0	21.0	93-146	104.8	20.1	80-125	133.1	19.9	103-156	129.9	22.0	100-158	132.2	21.1	102-160	6.88***
FBIS (0-50)	29.1	6.0	21-38	26.8	8.1	15-28	22.2	9.0	11-35	30.1	7.1	21-40	29.4	9.1	17-40	29.8	9.8	18-42	6.21**
SPSI-R:S (0-100)	51.1	9.0	40-64	55.8	9.8	44-71	62.1	10.5	48-78	52.5	8.3	40-65	53.4	9.2	42-67	53.0	10.8	39-68	3.30
SLOF (43-215)	124.8	19.4	98-150	136.8	21.0	106-165	155.1	23.1	113-183	123.8	19.0	97-151	123.0	24.0	95-156	120.3	28.0	93-158	7.01***
PANSS (43-215)	125.1	21.0	97-155	110.4	20.1	83-138	98.0	24.1	69-128	122.9	20.0	95-157	123.1	28.0	95-160	135.0	23.8	97-164	6.25**
Re-hospitalisation																			
<i>Number</i>	1.4	0.9	0-3	0.8	1.0	0-3	0.6	1.3	0-3	1.6	1.0	0-3	1.9	1.2	0-4	2.3	1.8	0-5	5.71**
<i>Duration</i> ^c	14.3	4.9	0-24	15.1	9.0	0-30	13.8	8.3	0-28	15.2	8.9	0-30	16.7	9.9	0-35	15.0	10.8	0-40	3.73
<i>Total number of patients being hospitalised</i>	22			14			8			24			23			19			Time 1: 3.0 [#] Time 2: 16.89 [#] ** Time 3: 24.33 [#] ***
Medication ^d	8.1	5.2	2.0-18.0	7.2	5.0	2.2-18.5	7.0	5.2	1.0-16.5	8.2	4.8	3.0-18.5	8.0	5.6	2.0-20.2	8.8	6.3	2.0-22.3	3.95

SPBB= Self-help Problem-solving Based Bibliotherapy; 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 intervention; Time 3= 6 months after intervention.

^a For ECI, the higher the mean score the more negative the appraisal of family carers to their caregiving experiences.

^b Possible range of scores of each scale indicated in parenthesis.

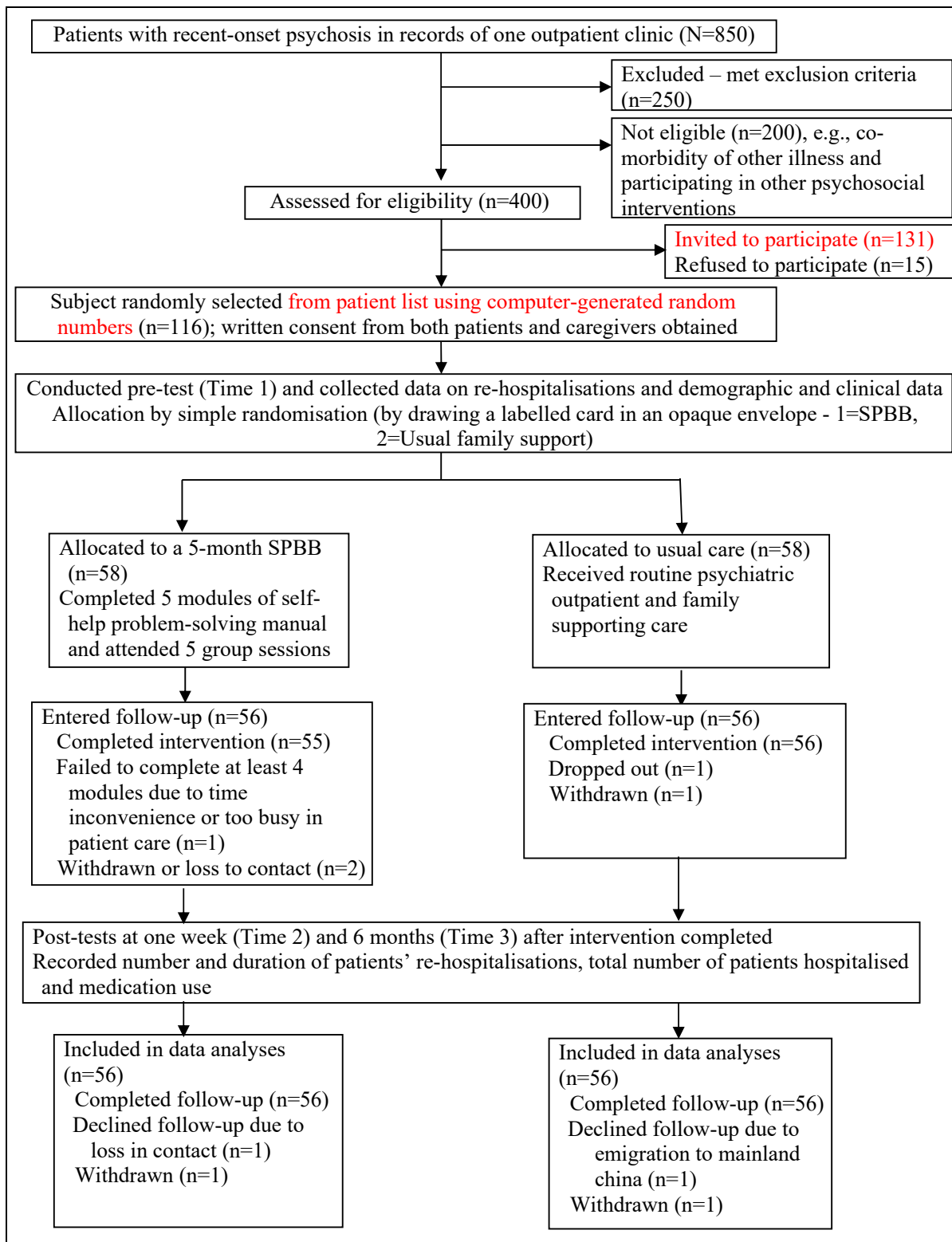
^c Duration of re-admissions in a psychiatric hospital or in-patient unit at Times 1,2 and 3, in terms of average days of hospital stay over the past 6 months.

°Medication scores were based on the converted haloperidol equivalents, as recommended by Bezchlibnyk-Butler et al. (2007).

#Value of Mann-Whitney U test for comparison of total number of patients hospitalised over the past six months measured at Times 1, 2 and 3.

* $p < 0.01$, ** $p < 0.005$, *** $p < 0.001$.

Figure 1. Flow diagram of the procedure of this randomised controlled trial



SPBB= Self-help Problem-solving Based Bibliotherapy.