Psychiatry Research ■ (■■■■) ■■■–■■■

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

# A randomized controlled clinical trial of a nurse-led structured psychosocial intervention program for people with first-onset mental illness in psychiatric outpatient clinics

Wai-Tong Chien *, Daniel Bressington

*School of Nursing, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong S.A.R, China*

ARTICLE INFO

*Article history:*
Received 17 November 2014
Received in revised form
19 May 2015
Accepted 7 July 2015

*Keywords:*
Controlled trial
First-episode mental illness
Insight into illness
Nurse-led program
Psychosocial intervention
Quality of life

ABSTRACT

This study aimed to test the effectiveness of a nurse-led structured psychosocial intervention program in Chinese patients with first-onset mental illness. A single-blind, parallel group, randomized controlled trial design was used. The study involved 180 participants with mild to moderate–severe symptoms of psychotic or mood disorders who were newly referred to two psychiatric outpatient clinics in Hong Kong. Patients were randomly assigned to either an eight-session nurse-led psychosocial intervention program (plus usual care) or usual psychiatric outpatient care (both $n=90$). The primary outcome was psychiatric symptoms. Outcomes were measured at recruitment, one week and 12 months post-intervention. Patients in the psychosocial intervention group reported statistically significant improvements in symptoms compared to treatment as usual. There were also significant improvements in illness insight and perceived quality of life and reduction in length of re-hospitalizations over the 12-month follow-up. The findings provide evidence that the nurse-led psychosocial intervention program resulted in improved health outcomes in Chinese patients with first-onset mental illness.



## 1. Introduction

People with first-and recent-onset serious mental health problems can experience significant delays in receiving treatment. Some of the reasons for these delays include family and/or patient reluctance to seek treatment and limited or non-accessible mental health services. This is concerning because a longer duration of untreated symptoms has been repeatedly shown to result in high relapse rates and poor long-term outcomes (Frank et al., 2009; Bird et al., 2010; Chen et al., 2011). Therefore, there is a clear need for appropriate early clinical intervention in order to improve prognosis. With this intention, international efforts have been made to reform community mental health services in order to avoid these unnecessary delays in treatment (Larsen et al., 2001).

Perhaps one of the best examples of such reforms is the widespread introduction of early intervention services (EIS) for psychosis and other serious mental disorders across much of the developed world (Marshall and Rathbone, 2011; Stafford et al., 2013). Some studies that evaluate EIS delivered by large community-based mental health teams have demonstrated significant reductions in psychiatric symptoms and relapse rates when compared to standard treatment (Bertelsen et al., 2008; Bird et al., 2010). A Cochrane review of early intervention for psychosis (Marshall and Rathbone, 2011a) also concluded that there was promising evidence of the effectiveness of specialized early intervention services, particularly where treatments were stage-specific and engaged families. Similarly, an earlier Cochrane review of interventions to help people recognize the early warning signs of bipolar disorder (Morriss et al., 2007) reported the benefits of intervening early to prevent hospitalizations and improve functioning. A more recent systematic review and meta-analysis of early interventions to prevent psychosis (Stafford et al., 2013) concurred with the earlier studies in reporting that although the evidence is not conclusive, it is possible that psychological interventions can improve mental health outcomes when applied promptly after the first emergence of symptoms.

There is also some limited evidence that services provided by similar specialized multidisciplinary teams in Hong Kong (e.g., Early Assessment Service for Youth) result in improvements in suicide rates, levels of symptoms and gains in employment (Chen et al., 2011). Some health economic studies also show that EIS for psychosis have the potential to reduce costs associated with losses in productivity and other healthcare costs (Mihalopoulos et al., 2009; McCrone et al., 2010, 2011), but regrettably such specialized services are not always in existence or available and therefore many people with first-episode psychosis or other early onset

* Corresponding author. Fax: +852 2364 9663.
*E-mail address:* wai.tong.chien@polyu.edu.hk (W.-T. Chien).

http://dx.doi.org/10.1016/j.psychres.2015.07.012
0165-1781/

mental illnesses are referred to usual psychiatric outpatient services.

Despite early treatment being essential for people with recent-onset mental illness, many developed countries similar to Hong Kong still have long waiting lists for newly referred cases in general psychiatric outpatient services. This can result in delays of four to 12 weeks for service users to receive their first psychiatric consultation and/or subsequent treatment (Aron et al., 2009; Hospital Authority, Hong Kong, 2013). In Hong Kong the period of waiting time is determined by the urgency or priority of care established by initial mental health assessments conducted in outpatient clinics (Chien and Leung, 2013) and therefore patients not deemed as being at significant risk often face considerable delays in accessing psychiatric treatment.

To address these gaps in services and provide as early intervention as possible, nurse-led mental health services could be a useful alternative approach when specialist EIS provided by larger multi-disciplinary mental health care teams are not available. However, there is still relatively scant evidence about the efficacy of approaches in the care of people newly referred to psychiatric services with an acute episode of first-onset mental illness (Haddock and Lewis, 2005; Bertelsen et al., 2008; Chien et al., 2012). One of the few studies on a nurse-led self-harm assessment and treatment program in the United Kingdom indicated that the service was potentially cost-effective and resulted in a significant reduction of self-harm behaviors and physical injuries (Griffiths et al., 2001).

A similar encouraging pilot study (Chien and Leung, 2013) tested the effects and feasibility of a nurse-led, needs-based psycho-education program for first-onset Chinese schizophrenia sufferers and their families in Hong Kong with a six-month follow-up. The 48 participants in the intervention group reported statistically significant reductions in psychopathology, improved attitudes toward their illness and reduced re-hospitalization rates, when compared to those patients receiving treatment as usual. This earlier study utilized a range of nurse-led psychosocial interventions, which were underpinned by psycho-educational and motivational interviewing approaches. The previous pilot study also used elements of manualized adherence therapy and medication management interventions, which in some settings have been shown to be promising in improving medication adherence, reducing psychopathology and encouraging engagement with services (Maneesakorn et al., 2007; Harris et al., 2009; Gray et al., 2010; Brown et al., 2013).

In this study we have built on our earlier work (Chien et al., 2012; Chien and Leung, 2013) and robustly tested a structured psychosocial intervention program using a similar combination of clinical approaches in a larger sample size of people who need to access immediate support. We decided to include patients in this study that had been newly referred with acute psychotic or affective symptoms but who had yet to receive an established psychiatric diagnosis. This choice was based on the fact that delays in accessing a psychiatrist for people not deemed as being at considerable risk are common Hong Kong and Western psychiatric outpatient care services and an early intervention as such provided in this study would be beneficial for people with first-onset mental illness in the absence of a formal psychiatric diagnosis. This approach could also minimize the risk of prolonged duration of untreated illness and enhance the generalisability of the intervention beyond a discreet group of patients. This randomized controlled trial therefore aimed to investigate the effects of a nurse-led psychosocial intervention program (PIP) for newly-referred Chinese patients with mild to moderate–severe symptoms of first-onset mental illness.

## 2. Methods

### 2.1. Trial design

This study used a single-blind, parallel group randomized controlled trial with repeated-measures, control group design. The primary objective was to investigate the effects of the PIP on patients' symptoms over a 12-month period compared to usual psychiatric outpatient care. This controlled trial also tested secondary outcomes relating to the effects on patients' insight into illness and treatment, perceived self-efficacy, quality of life, and re-hospitalization rates over the 12-month follow-up. Assessment of patients' outcomes was performed by a researcher (first author) blind to group allocation. The procedure of this controlled trial is summarized and presented in Figure 1. The controlled trial was registered at ClinicalTrials.gov Protocol Registration and Results System (ID: NCT02275390). There were no deviations from, or amendments to the original study protocol after the trial commenced.

### 2.2. Study setting

This study was conducted in two regional general psychiatric outpatient clinics (OPDs) serving a population of approximately 800,000 (12% of the total population) in Hong Kong. Recruitment was commenced in December 2011 and ended in August 2012.The intervention was delivered between January and December 2012; and the follow-ups of patient outcomes were completed by the end of December 2013.

### 2.3. Ethical approval

The study was approved by the Human Subject Research Ethics Committee of The Hong Kong Polytechnic University and the outpatient clinics under study (KC/KE-10-0024/ER-7).

### 2.4. Inclusion criteria

The inclusion criteria for patients attending the OPDs were those who were: aged 18–60 years, with capacity to provide informed consent, able to understand Cantonese/Mandarin, having a first-onset of mental illness (psychotic and mood disorders) within the past three months, newly referred to mental healthcare services, and presenting at least mild to moderate–severe levels of psychiatric symptoms (i.e., Brief Psychiatric Rating Scale score of $>25$ out of 126 and/or Chinese version of the Beck Depression Inventory-II scores of $>10$ out of 63), but with no history of and low risk of suicide and self-harm (Overall and Gorham, 1962; Wu and Chang, 2008).

Patients who did not meet the aforementioned inclusion criteria or who were receiving other psychosocial interventions organized by the clinics or other healthcare organizations, or who were classified as the highest priority of psychiatric consultation and treatment (i.e., starting their treatment and care plan with their attending psychiatrist and clinic nurse within one week) were excluded from the study. The urgency or priority of care was established by the OPD staff from the information included in the referral letters and via the initial mental health assessments conducted in the clinics.

### 2.5. Recruitment process

A total of 480 Chinese patients were referred to and attended the two regional psychiatric outpatient clinics (OPDs) in Hong Kong between December 2011 and August 2012. The potential participants were assessed for suitability for study inclusion as per

Please cite this article as: Chien, W.-T., Bressington, D., A randomized controlled clinical trial of a nurse-led structured psychosocial intervention program for people with first-onset mental illness in psychiatric outpatient clinics. Psychiatry Research (2015), http://dx.doi.org/10.1016/j.psychres.2015.07.012