A Randomised Controlled Trial of a Mindfulness-based Intervention for People with Schizophrenia

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Background

Psychoeducation and other psychosocial interventions in schizophrenia are evidenced to improve patients' knowledge about the illness and relapse rate. Nevertheless, other benefits to patients, for example, their functioning and insight into illness, or to be substantive in a longer term, are inconsistent and thus remain unknown. The significance of mindfulness-based interventions and other cognitive therapies has been evidenced in treatments of a wide variety of chronic physical and mental (e.g., anxiety and post-traumatic stress syndrome) illnesses. These psychological approaches may be important for schizophrenia because these patients are often characterised by unexpectedly low adherence to treatments, or partially responsive to conventional psychiatric treatments/interventions, thus leading to a chronic course of illness and frequent relapses (*Lam & Chien, 2016*).

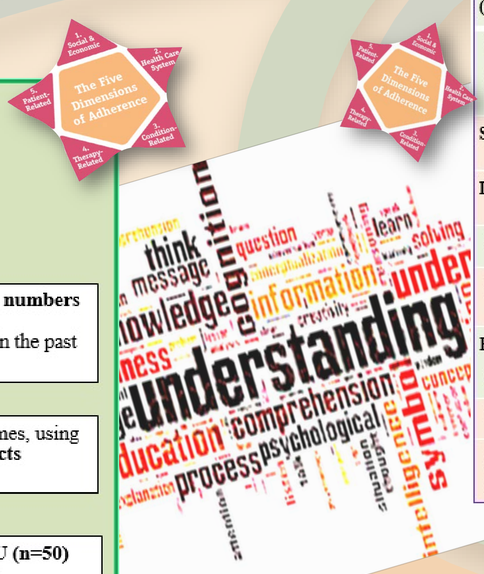
Aims of the Study

This three-arm clinical trial (RCT) tested the effects of a mindfulness-based psycho-education group program (MPGP) (in addition to usual care) for Chinese patients with early-stage schizophrenia (≤5 years of illness), compared to a conventional psycho-education group program (CPG) or treatment-as-usual (TAU) only, on several patient outcomes over 18 months follow-up.

Methods

Design. The multi-site RCT adopted a single-blind, three-arm and repeated-measures study design; and outcome analyses were based on intention-to-treat principle. The study was conducted at four psychiatric specialty clinics, i.e., two in Hong Kong and two in Jilin, China (subject recruitment: Sept 2013 - Jan 2014; and 18-month follow-up: Jan 2014 - Sept 2015). The trial procedure is summarised in *Figure 1* according to the CONSORT statement.

Figure 1. The CONSORT diagram of the Clinical Trial



Target Population with schizophrenia and its subtypes (n=4,800; 800-900 in each clinic)

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Assessed for eligibility (n=800 or 400 per city)
Found eligible (n=585; 250 and 235 in each city)
Refused to participate (n=15 and 16)

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Subject randomly selected from two patient lists using computer-generated random numbers (n=75 per city); written consent from patients obtained
Baseline assessment: demographic data, SLOF, ITAQ, PANSS, and re-hospitalization in the past six months

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Allocation by random numbers matching with patient lists in alphabetical order of surnames, using stochastic minimisation programme and balancing gender and symptoms **(n= 50 subjects assigned to each group)**

Allocated to a 6-month MPGP (n=50)	**Allocated to a 6-month CPG (n=50)**	**Allocated to TAU (n=50)**
Completed 12 biweekly, 2-hour group sessions of mindfulness-based psychoeducation	Completed 12 bi-weekly, 2-hour group sessions of conventional psychoeducation	Received **routine** psychiatric outpatient care only (12 weeks)
↓	↓	↓
Entered follow-up (n=47) *Completed intervention (n=45)* *Failed to complete at least 5 sessions due to time inconvenience or poor mental state (n=5)* *Loss to contact (n=3)*	**Entered follow-up (n=48)** *Completed intervention (n=44)* *Failed to complete at least 5 sessions due to time inconvenience or lack of motivation (n=6)* *Loss to contact (n=2)*	**Entered follow-up (n=47)** *Completed intervention (n=47)* *Dropped out (n=2)* *Withdrawn (n=1)*
↓	↓	↓
Included in data analyses (n=46) *Completed follow-up (n=46)* *Declined follow-up due to loss in contact (n=2)* *Withdrawn (n=1)*	Included in data analyses (n=46) *Completed follow-up (n=45)* *Declined follow-up due to moving out of the city (n=2)* *Withdrawn (n=2)*	Included in data analyses (n=45) *Completed follow-up (n=45)* *Declined follow-up due to emigration to China (n=1)* *Withdrawn (n=2)*

Post-tests at one week (Time 2), 9 months (Time 3) and 18 months (Time 4) post-intervention
Recorded number and duration of patients' re-hospitalisations, total number of patients hospitalised, and dosage and types of psychotropic medications Withdrawn (n=1)

ITAQ: Insight and Treatment Attitudes Questionnaire; PANSS: Positive and Negative Syndrome Scale; SLOF: Specific Level of Functioning Scale.

Sampling. After baseline measurement, eligible patients with schizophrenia spectrum disorders were randomly allocated into one of the three study groups (MPGP, CPG or TAU alone; *50 per group*). After completing 6-month interventions, most of them in the MPGP, CPG and TAU (n=47, 48 and 47, accordingly) continued the follow-ups; only a few lost/withdrew. Finally, 46 participants in both the MPGP and CPG and 45 in the TAU completed the 18-month follow-up.

Interventions. Participants received a 24-week (12 two-hour sessions every two weeks) *MPGP* (12-15 patients per group), adopted from the Kabat-Zinn's Mindfulness-Based Stress Reduction Program (MBSR) and modified for Chinese patients by integrating into a psycho-education group tested in Hong Kong (*Chien & Thompson, 2014*). The *CPG*, similar to the MPGP, consisted of 12 two-hour sessions (bi-weekly, 14-15 members per group) and adopted the psycho-education manual of *Lehman et al.'s (2004)* PORT program. The TAU consisted of usual psychiatric care received by all participants (n=150), which was found similar across the four clinics (in Hong Kong and Jilin).

Study outcomes and analyses. Participants' functioning (Specific Level of Functioning Scale, *SLOF*) and average number and duration of re-hospitalisations in the past 6 months; and their symptoms (Positive and Negative Syndrome Scale, *PANSS*) and insights into illness (Insight and Treatment Attitude Questionnaire, *ITAQ*) were measured at recruitment and one week (*Post-test 1*), 9 months (*Post-test 2*) and 18 months (*Post-test 3*) following the interventions. Interaction (Group x Time) treatment effects within- and between-group was tested with mixed-model MANOVA followed by Helmert's contrasts.

Results

137 of the 150 participants (91%) completed their interventions and all post-tests. Five and six participants (10% and 12%) in the MPGP and CPG, respectively, failed to complete >4 group sessions. Participants' mean ages were 25.4±6.8 years (range18 to 38 years; 54-56% male). Most of them (>80%) had <3 years of mental illness (2.4±1.8, range 4-60 months), and received oral antipsychotic medications (>50% with low to medium dosage of first-generation antipsychotics). Results of outcome analyses (at *Baseline and Post-tests 1* and *3*) are indicated in *Table 1*.

Table 1. Results of outcome analyses (N=136)

	MPGP (n=46)			CPG (n=46)			TAU (n=45)			
Instrument	**Baseline M (SD)**	**Post-test 1 M (SD)**	**Post-test 3 M (SD)**	**Baseline M (SD)**	**Post-test 1 M (SD)**	**Post-test 3 M (SD)**	**Baseline M (SD)**	**Post-test 1 M (SD)**	**Post-test 3 M (SD)**	**F (2,134)**
PANSS (30-210) [a]	92.3 (11.3)	74.1 (8.2)	58.9 (9.7)	91.2 (7.0)	82.5 (9.8)	79.1 (9.5)	91.3 (8.9)	97.2 (9.7)	101.2 (13.1)	*7.10***
Positive symptoms	25.1 (7.0)	19.5 (9.7)	13.2 (6.2)	26.4 (7.1)	22.5 (7.0)	20.8 (8.0)	25.8 (8.0)	26.8 (9.0)	30.9 (10.1)	*7.20***
Negative symptoms	20.8 (8.9)	17.0 (6.5)	18.2 (5.2)	19.2 (6.5)	18.5 (7.2)	19.3 (9.1)	21.0 (7.0)	22.3 (8.9)	26.0 (9.8)	*5.82***
SLOF (43-215)	128.5 (16.0)	147.5 (13.8)	179.1 (17.2)	130.0 (19.1)	140.1 (17.2)	152.2 (18.0)	130.1 (15.2)	132.1 (19.1)	122.5 (28.1)	*7.61***
ITAQ (0-22)	9.9 (1.9)	11.5 (4.5)	15.0 (6.1)	9.7 (2.0)	10.8 (4.2)	13.6 (6.4)	9.6 (1.9)	10.0 (2.9)	13.0 (4.8)	*6.80***
Insight to illness (0-12)	4.8 (1.1)	5.5 (2.0)	8.0 (2.0)	4.6 (1.8)	5.3 (3.2)	6.9 (2.2)	4.9 (1.3)	5.1 (2.0)	6.1 (2.3)	*6.50***
Treatment attitude (0-10)	5.1 (1.5)	6.0 (2.1)	7.0 (2.1)	5.1 (2.0)	5.5 (3.0)	6.7 (2.0)	4.7 (1.1)	4.9 (2.0)	6.9 (2.2)	*7.21***
Re-admission (in 6 mths.)										
Average Number	2.2 (1.3)	2.0 (1.1)	1.8 (1.0)	2.0 (1.2)	2.0 (1.1)	2.3 (1.5)	2.0 (1.1)	2.5 (1.9)	2.9 (1.9)	2.1
Length (days/month)	16.9 (6.8)	12.6 (5.0)	9.1 (4.1)	17.2 (7.0)	15.8 (9.1)	16.2 (8.1)	17.2 (9.2)	20.3 (10.0)	24.0 (10.1)	*5.62***
No. of patients hospitalised	16	11	6	17	13	12	18	18	19	*9.35***

[a] Possible score range of each measure; * p< 0.05, ** p<0.01. ITAQ: Insight and Treatment Attitudes Questionnaire; PANSS: Positive and Negative Syndrome Scale; SLOF: Specific Level of Functioning Scale.

A significant interactive (Group x Time) treatment effect on the set of six outcome scores between the three study groups, F(6,135)=8.13, p=0.0007 (Wilks' λ=0.96; partial η^2=0.58, a large effect size). Referring to Table 1, the MPGP had significant greater improvement in functioning (p=0.01) and insight into illness/treatment (p=0.01), as well as reductions of length of re-hospitalisations and total number of hospitalized patients (both p=0.008) and psychotic symptoms (p=0.009), than the CGP and TAU over 18 months. Contrasts tests results also revealed that the MPGP group had significant greater improvements in functioning, duration of hospitalisations, symptom severity, and insight into illness/ treatment than the other two groups at the 18-month follow-up (*Post-test 3*).

Discussion

This multi-centre RCT was the first one conducted to test the benefits of this mindfulness-based psychoeducation intervention (MPGP) for people with early-stage schizophrenia, particularly in a longer term follow-up. Comparing to conventional psychoeducation group and TAU only, the patient outcomes in the MPGP are very positive and highly encouraging over the 18-month follow-up, especially their functioning and hospitalisation rates (primary outcomes). These results may fill in the knowledge gap that psychosocial intervention can only show significant short to medium term effects in psychiatric symptoms and relapse prevention in schizophrenia, as indicated in recent systematic reviews (*Lam & Chien, 2016*).

Conclusions

Despite a few limitations noted (e.g., voluntary and highly educated subjects and minimal intervention adherence monitoring), this controlled trial supports that the mindfulness-based program (MPGP) can improve the psychosocial health and functioning and thus community-based rehabilitation of patients with early schizophrenia and its subtypes. The findings support further research on mindfulness-based interventions for people with psychotic disorders with wider socio-demographic, ethnic and clinical characteristics.

References

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