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Effectiveness of an Assertive Community Treatment program for people with severe schizophrenia in mainland China – a 12-month randomized controlled trial

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Abstract

Background. Assertive Community Treatment (ACT) is an evidence-based treatment program for people with severe mental illness developed in high-income countries. We report the first randomized controlled trial of ACT in mainland China.

Methods. Sixty outpatients with schizophrenia with severe functional impairments or frequent hospitalizations were randomly assigned to ACT ($n = 30$) or standard community treatment ($n = 30$). The severity of symptoms and level of social functioning were assessed at baseline and every 3 months during the 1-year study. The primary outcome was the duration of hospital readmission. Secondary outcomes included a pre-post change in symptom severity, the rates of symptom relapse and gainful employment, social and occupational functioning, and quality of life of family caregivers.

Results. Based on a modified intention-to-treat analysis, the outcomes for ACT were significantly better than those of standard community treatment. ACT patients were less likely to be readmitted [3.3% (1/30) *v.* 25.0% (7/28), Fisher's exact test $p = 0.023$], had a shorter mean readmission time [2.4 (13.3) *v.* 30.7 (66.9) days], were less likely to relapse [6.7% (2/30) *v.* 28.6% (8/28), Fisher's exact test $p = 0.038$], and had shorter mean time in relapse [3.5 (14.6) *v.* 34.4 (70.6) days]. The ACT group also had significantly longer times re-employed and greater symptomatic improvement and their caregivers experienced a greater improvement in their quality of life.

Conclusion. Our results show that culturally adapted ACT is both feasible and effective for individuals with severe schizophrenia in urban China. Replication studies with larger samples and longer duration of follow up are warranted.

Introduction

The World Health Organization estimates that, by 2020, schizophrenia will account for 1.3% of the total disease burden (Murray and Lopez, 1996). In China, 6 million individuals suffer from schizophrenia: 80% of them with moderate to severe disability; 40% of them have never received treatment (Phillips *et al.*, 2009). Rapidly rising treatment costs and the social hardships experienced by patients and their families (Xu *et al.*, 2013) have made schizophrenia a major public health crisis in China (Xiang *et al.*, 2012). However, the community mental health service sector in China is underdeveloped (Phillips, 2004) and lacking integration or coordination among service providers (Liu *et al.*, 2011). Other daunting factors include shortages of trained mental health personnel and allied professionals, inadequate and outdated training, the low level of public awareness about mental illness, and widespread stigma and discrimination against individuals with mental illnesses and their families (Xiang *et al.*, 2012).

Recent efforts to address these problems included the passage of China's first National Mental Health Law in 2013 (Chen *et al.*, 2012; Phillips *et al.*, 2013), and growing prioritization of mental health funding in the National Five-Year Plan for Health (Tse *et al.*, 2013; Xiong and Phillips, 2016). Development of the '686 project' in 2005 – the world's largest community case-management program for individuals with severe mental illnesses (SMI) (Good and Good, 2012) has by now registered up to one-half of the people with SMI in the country, providing some of them with free psychiatric medications and quarterly follow-up at home or in a clinic.

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It has identified extreme cases and 'unlocked' many individuals who had previously been held in chains and restraints within their homes due to a lack of treatment options (Guan *et al.*, 2015). Despite these improvements, a recent study suggests that at least 20% of the individuals with SMI in China remain hard to treat and do not adhere to medications, resulting in severe social dysfunction and burden (Wang *et al.*, 2016).

Assertive Community Treatment (ACT) is well-studied and considered by many the 'gold standard' treatment for people with SMI (Dixon, 2000). However, there are on-going debates whether ACT is universally effective. While results of randomized controlled trials (RCT) in North America and Australia have consistently found that ACT is effective in reducing hospitalization rates and improve patient functioning (e.g. Issakidis *et al.*, 1999; Bond *et al.*, 2001; Dixon *et al.*, 2010), research in Europe, particularly those from the UK did not support the same (e.g. Burns, 2010; Dieterich *et al.*, 2017). With this backdrop of controversy taking place in western, high-income countries, there are notable ACT research in other parts of the world, in culturally and economically diverse settings, such as the RCTs in Japan (Ito *et al.*, 2011) and South Africa (Botha *et al.*, 2014), and non-RCTs in Singapore (Low *et al.*, 2013), Korea (Kim *et al.*, 2015), and Hong Kong (Liem and Lee, 2013). However, it remains unknown whether ACT is effective in mainland China, where social, cultural, and economic factors are vastly different. To address this issue, we carried out an uncontrolled, 6-month pilot study to explore the feasibility of ACT in mainland China (Zhao *et al.*, 2015). This pilot also focused on making family psychoeducation and consultation a core part of the ACT services to reflect the culturally distinct needs of the Chinese setting, and found significant positive results. The current paper aims to further contribute to the global examination of the ACT model, and reports on the results of a subsequent 12-month RCT – the first RCT study of ACT in China.

Methods

Study design

This parallel-group RCT compared the effectiveness of ACT for schizophrenia to that of treatment as usual. The study was approved by the Ethics Committee of the Second Xiangya Hospital of Central South University, and was registered at the Chinese Clinical Trials Registry Center (ChiCTR-TRC-13003407).

Study population and recruitment

The trial was carried out in two urban districts of Changsha, a mid-sized city in the south-central province of Hunan, China, with 475 663 and 523, 730 inhabitants (2010 census), respectively. The inclusion criteria for patients were: (1) age 18–45 years; (2) diagnosis of schizophrenia based on the Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV); (3) no organic brain disorder, mental retardation, severe head trauma, or personality disorder [based on chart reviews and using Semi-structured Clinical Interview for DSM-IV for personality disorders (SCID-II)]; (4) significant functional impairment; (5) have one or more indicators of a need for continuous high level of services [criteria for (4) and (5) were based on standard ACT Manual description (Allness and Knoedler, 2003) and confirmed by clinical assessment, see details in the online Supplementary materials]; (6) no co-residing family member with a mental illness [using SCID Interview for DSM-IV-TR Axis I Disorders Non-patient Edition (SCID-I/NP)]; and (7) both the patient and a co-residing family caregiver provide written informed consent to participate. The participating family caregivers were 18 years of age or older and had to be living with and caring for the patient for at least the last 3 months.

Between April 2013 and July 2013, we recruited 60 patients with schizophrenia from a list of 1023 patients registered in their local community health offices in the two districts. The qualified participants completed the baseline interviews and were randomly assigned to the ACT intervention group ($n = 30$) or the standard-care control group ($n = 30$). The randomization protocol was implemented by two researchers unaffiliated with this study: one prepared an SPSS-generated restricted random assignment sequence to balance time of study entry and sample sizes on each arm of the study, and the other prepared sequentially numbered, opaque sealed envelopes for concealing the randomization sequence. Participants were informed of their group assignment at the end of the baseline interview after the written informed consent was signed. Figure 1 shows the CONSORT flowchart for the study. The high rate of refusal to participate [47% (478/1023)] is common in community-based psychiatric studies in mainland China, likely reflecting a heavy sense of stigma, and mistrust and unfamiliarity with mental health research (Zhang *et al.*, 2002).

Study intervention and follow up

ACT: The intervention group received free culturally adapted ACT services that included two to three community/home visits per week to deliver usual ACT care. The ACT services were individually tailored, informed by Recovery principles (Salyers and Tsemberis, 2007) and aimed to improve both clinical outcome and quality of lives for patients. The services generally included clinical assessments and crisis intervention (e.g. timely responses and home visits), psychosocial assistance, supportive counseling, and family support (e.g. teaching strategies coping with stigma, setting goals for employment, empowering for treatment decisions, etc.), and functional assistance (accompanied medical appointments, social entitlement securements, etc.) and 2-h family psychoeducation sessions per month for 12 months (Chow *et al.*, 2010; Zhao *et al.*, 2015). All participants and their family caregivers in the ACT intervention group completed the 1-year study. The intervention was carried out by the ACT team from the Second Xiangya Hospital in Changsha, Hunan. The team consisted of a team leader who was a psychiatrist, a part-time psychiatrist, a part-time psychiatric nurse, two full-time clinical psychologists, three full-time social workers, and a part-time employment specialist. Experts from an established ACT team from Mount Sinai Hospital, Toronto, Canada provided training and supervision for the treatment team; one of whom also performed an on-site assessment of the fidelity of the study ACT program using the Tool for Measurement of Assertive Community Treatment (TMACT, Monroe-DeVita *et al.*, 2011). The results of this assessment were used to provide feedback and to improve the quality of the services.

Treatment as usual (*TAU*): Participants assigned to the TAU group received existing '686 program' community mental health services available in their communities free of charge. In theory this treatment includes outpatient visits to a psychiatric clinic every 1–3 months (offered by the Ministry of Civil Affairs), and home visits by public health professionals every 1–3 months

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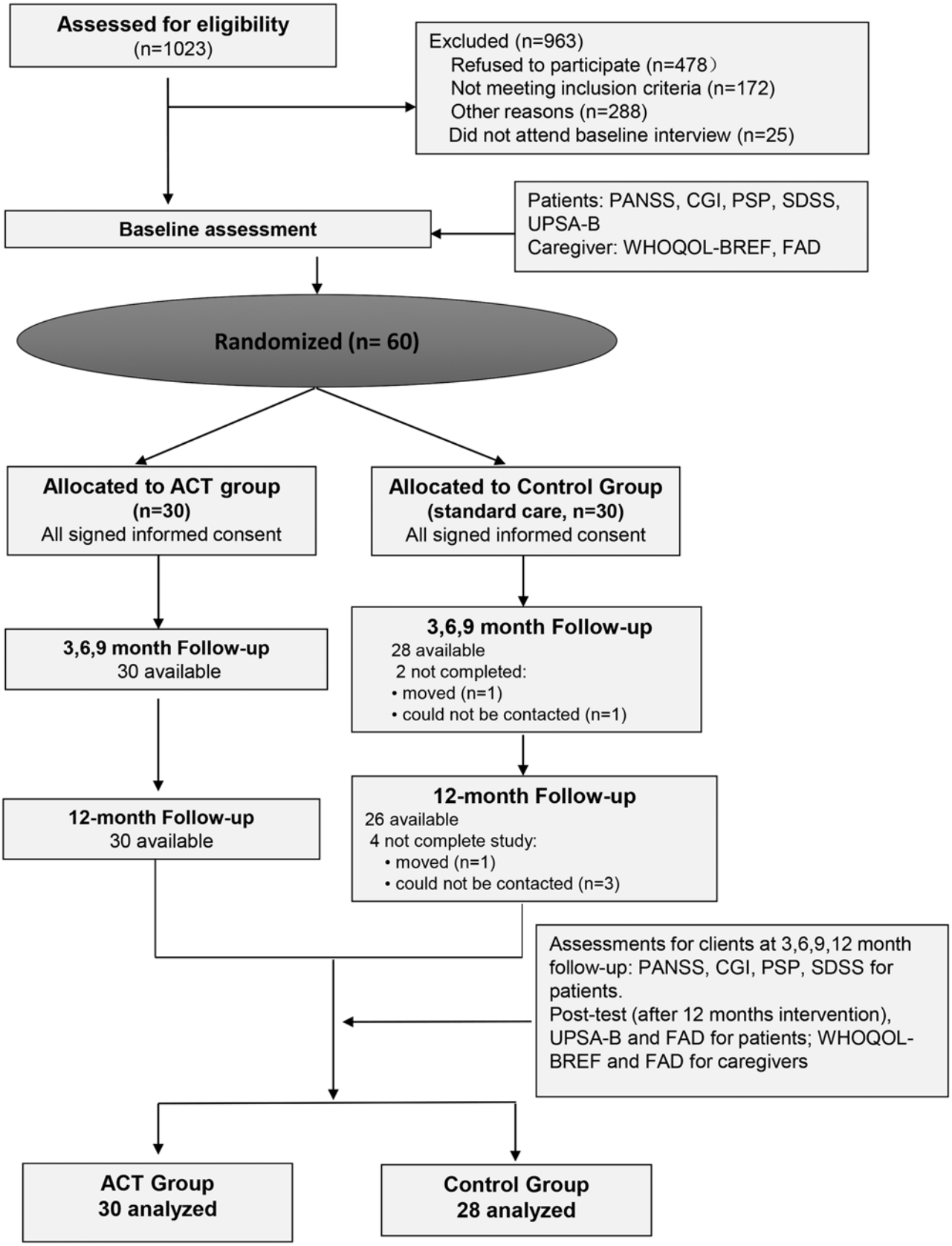

Fig. 1. CONSORT flowchart of the study. ACT, Assertive Community Treatment; PSP, Personal and Social Performance Scale; PANSS, Positive and Negative Syndrome Scale; UPSA-B, Performance Skill Assessment-Brief; CGI, Clinical Global Impression; WHOQOL – BREF, WHO Brief Quality of Life; SDSS, Social Disability Screening Schedule; FAD, Family Assessment Device.

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(offered by '686 program'); during these visits the target individual is assessed, provided non-specific counselling, and given free psychotropic medications. However, not all individuals enrolled in the '686 program' actually receive these services (due to lack of local mental health manpower and unwillingness on the part of the patient or the family). To ensure that all patients in the control group obtained standard '686 program' level of care, the study team did a follow-up telephone call with each individual monthly and a home visit every 3 months over the 12-month follow-up period. Of the 30 controls, 26 completed the study, one could not be located after the baseline assessment, one moved out of the district after the baseline assessment, and two could not be contacted after the 9-month assessment. The two patients who were not follow-up right after baseline were not included in the modified intent-to-treat outcome analyses. For the two participants who were lost after the 9-month assessment, they are included in the analyses proposed in the study. Their data for the 12-month were regarded as missing.

Study outcomes and data collection

Mean per patient readmission days in each group was the primary outcome variable. As is true for community-dwelling individuals with severe mental illness throughout China, hospitalization decisions were made by the patients' family members and other caregivers based on the severity of their symptoms and level of social dysfunction; the ACT treatment teams did not unilaterally admit or send patients to the hospital.

Other outcomes included:

Relapse days. The number of days over the 12-months the individual experienced any of the following: hospitalized for a psychiatric problem; an increase of 25% or more over baseline in the total score of the Positive and Negative Symptoms Scale (PANSS, Kay *et al.*, 1987) or – if the baseline score was less than 40 – an increase of 10 points or more in the total PANSS score; deliberate self-injury; suicidal or homicidal ideation that the investigator judged as clinically significant; violent behavior resulting in clinically significant injury to another person or property damage; or a rating on the Clinical Global Impression (CGI) of 6 ('much worse') or 7 ('very much worse') (Guy, 1976). Days in relapse were recorded based on reports of the patient and his/her family members at the time of assessment.

Re-employment days. Number of days of any form of paid employment, whether temporary or regular over the 12-months.

Severity of psychiatric symptoms and social dysfunction. Patients' psychiatric symptoms and social functioning were evaluated at baseline and every 3 months thereafter using PANSS, CGI, the Personal and Social Performance Scale (PSP, Tianmei *et al.*, 2011) and the Social Disability Screening Schedule (SDSS, World Health Organization, 1988). At baseline and at the 12-month follow-up, patients also completed the Family Assessment Device (FAD, Mansfield *et al.*, 2015) and the UCSD Performance-Based Skills Assessment-Brief form (UPSA-B, Mausbach *et al.*, 2007).

Family relationships and the caregiver quality of life. At baseline and at the 12-month follow-up, the family caregiver completed the FAD, and the World Health Organization Quality of Life (WHOQOL – BREF) scale (The WHOQOL Group, 1998).

These evaluations were carried out by two evaluators who were unaffiliated with the study and their blinding about the treatment status of patients was strictly maintained throughout the study.

Statistical analysis

Data analyses were performed using SPSS version 18.0 (SPSS, Chicago, IL, USA) and STATA 14.0 (Stata Corp LP, College Station, TX, USA). Consistent with statistical methods employed by other ACT RCT studies, differences between the groups at baseline were compared using independent-samples *t* tests or nonparametric tests (i.e. Mann–Whitney *U* tests); the proportions of patients in the two groups that experienced readmission/relapse/reemployment over the follow-up period were compared using Fisher's exact tests.

In addition, Cox regression was employed to examine the relationship of ACT treatment on the risk (hazard) of readmission, relapse, and reemployment after controlling for social demographic and clinical characteristics (i.e. age, duration of illness, number of prior hospitalizations, and baseline PANSS and SDSS total scores). Time to first relapse, readmission, and reemployment after the baseline assessment were assessed using Kaplan–Meier survival analysis, censored at 365 days if the event did not occur during the full 12 months of follow-up. Mixed effect model was used to analyze the results for variables assessed at baseline and at 3, 6, 9, and 12 months of follow-up (i.e. PANSS, PSP, SDSS, and CGI), with the baseline score and the duration of illness used as covariates to obtain estimates of change from baseline – the 'intervention effect'. UNIANOVA was used to analyze variables assessed at baseline and at the 12-month follow-up (i.e. UPSA-B and FAD for patients; and WHOQOL–BREF and FAD for family caregivers). We used Holm–Bonferroni test to check for multiple comparison type I errors.

Results

Fidelity of the ACT program

The mean per item score of the 47-item TMACT fidelity assessment (range 1–5) is classified as 'not certified' (less than 3), 'basic fidelity' (3.0–3.6), 'moderate fidelity' (3.7–4.2), or 'high fidelity' (4.3 or higher). The study team had a score of 3.8, indicating low-moderate fidelity. However, 6 of the 47 TMACT items are culturally less relevant in China – the provision of supportive housing (item EP8), availability of a substance abuse specialist (items ST1, ST2, and ST3), and programming for dual diagnosis patients (item EP1 and EP4) – because virtually all patients with severe mental illness live with family members, and alcohol and drug abuse (consequently, dual diagnosis) is extremely rare (none for the study participants had dual diagnoses). When these six items are removed the revised 41-item TMACT fidelity score increased to 4.1, suggesting high-moderate fidelity (see online Supplementary Table S1). Of note, the study team received a TMACT score of 3 or less on the following: 'Team Leader On Team', 'Office Based Program Assistance', and 'Frequency of Contact' (due to lack of human resources and funding for fuller staffing and services); 'Peer Specialist on Team' (due to non-availability of such professional identity in China and broader stigma issues); and 'Full responsibility for 'Psychiatric Services', and 'Crisis Services' (due to funding and systemic and cultural practices that families took on typical responsibility for help seeking with anyone and at any time they wish, not solely relying on ACT team).

Demographic, socio-economic, and baseline clinical characteristics of client and caregiver participants

As shown in Table 1, with the exception of a longer mean (S.D.) duration of illness in the ACT group compared with that in the

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Table 1. Demographic, socio-economic, and clinical characteristics of patients and their caregivers in the ACT (Assertive Community Treatment) and control groups

Characteristics	ACT group ($n = 30$)		Control group ($n = 30$)				
Patients							
	N	%	*N*	%	Statistic	Value	*p*
Gender							
Male	21	70.0	20	66.7	x^2	0.08	0.781
Female	9	30.0	10	33.3			
Marriage							
Single	27	90.0	26	86.7	Fisher Exact test		0.671
Married	1	3.3	0	0.0			
Divorced	2	6.6	4	13.3			
Previous work experience							
Never	14	46.7	14	46.7	x^2	0.00	1.000
Ever	16	53.3	16	53.3			
	Mean	S.D.	Mean	S.D.			
Age	29.2	4.3	30.2	7.0	*t*	−0.20	0.841
Years of education	12.0	3.5	11.1	3.3	*t*	−0.78	0.380
Years duration of illness	9.8	3.6	7.5	4.4	*t*	**−2.09**	**0.037**
Number of hospitalizations	4.2	2.3	3.3	1.9	*t*	−1.62	0.104
Number of hospitalizations in last two years	1.2	1.1	1.2	1.1	*t*	−0.26	0.798
Caregivers							
Age	58.5	7.3	55.5	8.3	*t*	1.53	0.132
	N	%	*N*	%			
Age group							
35–45	0	0.0	2	6.7	x^2	2.56	0.476
46–55	12	40.0	14	46.7			
56–65	13	43.3	9	30.0			
66 or above	5	16.7	5	16.7			
Biological relationship							
Father	9	30.0	8	26.6	x^2	0.08	0.959
Mother	19	63.3	20	66.7			
Siblings	2	6.7	2	6.7			
Economic condition							
Low-income family[a]	12	40.0	16	53.3	x^2	1.07	0.301
Middle or high-income family	18	60.0	14	46.7			

[a]Low-income family refers to the family being entitled to basic living allowances for urban residents in Changsha. Significant *P* values (< 0.05) are in bold.

control group [9.8 (3.6) *v.* 7.5 (4.4) years, $t = 2.09$, $p = 0.037$], there were no significant demographic differences between the patients in the two groups. There were also no significant differences in the age of the family caregiver, the relationship of the family caregiver with the patient, or the economic status of the patients' families. Table 2 shows that there were no significant differences at baseline between the two groups in terms of clinical symptoms, social functioning, family functioning, and quality of life of the caregivers.

Occurrence, duration, and timing of hospital admission, relapse, and re-employment

One of the 30 patients in the ACT group and seven of the 28 patients in the control group were readmitted to hospital over the follow-up period: total admission days in the ACT and control groups were 73 and 859, respectively. The proportion of readmissions was significantly lower in the ACT group than in the control group (3.3% *v.* 25.0%, Fisher's exact test $p = 0.023$). The mean

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Table 2. Comparison of the mean (S.D.) scores of the various clinical and social functioning measures at baseline in the Assertive Community Treatment (ACT) and control groups

	ACT group($n = 30$)		Control group ($n = 30$)			
SCALE/Subscale	Mean	S.D.	Mean	S.D.	*t*	*P*
Patients						
PANSS						
Total score	71.1	10.8	74.7	14.6	1.10	0.277
Positive scale	15.8	5.4	16.9	6.1	0.74	0.460
Negative scale	21.2	4.9	22.0	5.2	0.64	0.524
General psychopathology scale	34.2	5.2	35.9	7.9	0.98	0.329
CGI	4.8	0.7	4.8	0.8	0.10[a]	0.917
SDSS	12.0	1.7	12.8	2.0	1.62[a]	0.105
PSP	53.8	7.0	53.2	10.4	0.64[a]	0.523
UPSA-B	12.0	4.0	11.1	4.8	0.60[a]	0.547
FAD						
Overall score	2.4	0.4	2.4	0.3	0.35	0.730
Problem solving	2.3	0.5	2.2	0.4	0.81	0.421
Communication	2.5	0.5	2.3	0.4	1.60	0.114
Roles	2.3	0.4	2.4	0.3	0.74	0.461
Affective responsiveness	2.6	0.6	2.4	0.6	1.03	0.307
Affective involvement	2.6	0.5	2.5	0.4	1.01	0.315
Behavioral control	2.4	0.4	2.5	0.4	1.03	0.306
General functioning	2.3	0.4	2.3	0.5	0.45	0.658
Family caregivers						
WHOQOL – BREF						
Total score	55.4	11.7	53.0	12.6	0.76	0.452
Physical	58.3	14.7	54.2	14.2	1.12	0.268
Psychology	53.9	14.1	55.1	16.9	0.51[a]	0.608
Social relations	60.8	12.8	57.8	15.3	0.75[a]	0.451
Environment	48.5	13.8	45.0	16.5	1.34[a]	0.180
SELF-REPORT QUALITY OF LIFE	71.8	12.1	70.8	12.1	0.32[a]	0.750
FAD						
Overall score	2.3	0.3	2.3	0.2	0.01	0.992
Problem solving	2.2	0.4	2.1	0.3	1.28	0.206
Communication	2.3	0.3	2.2	0.3	0.61	0.545
Roles	2.4	0.4	2.5	0.2	−0.92	0.360
Affective responsiveness	2.5	0.4	2.4	0.3	1.00	0.321
Affective involvement	2.4	0.4	2.5	0.3	−1.81	0.075
Behavioral control	2.4	0.3	2.4	0.2	0.11	0.913
General functioning	2.2	0.4	2.2	0.3	0.25	0.807

PANSS, Positive and Negative Syndrome Scale; CGI, Clinical Global Impression; SDSS, Social Disability Screening Schedule; PSP, Personal and Social Performance Scale; UPSA-B, Performance Skill Assessment-Brief; WHOQOL – BREF, WHO Brief Quality of Life; FAD, Family Assessment Device.
[a]2-independent samples nonparametric test (Mann–Whitney *U* test) for the non-normally distributed variables

(S.D.) day of readmission in the ACT group was 2.4 (13.3) days, while it was 30.7 (66.9) days in the control group. The Kaplan–Meier survival analysis for time to readmission (see Panel A of Fig. 2) found that the mean (S.E.) time to the first admission was significantly longer in the ACT group than in the control group [364 (1.3) *v.* 300 (22.9) days, log-rank $\chi^2 = 5.89$, $p = 0.015$].

Two patients in the ACT group and eight patients in the control group met the 'relapse' definition over the 12-month follow-up

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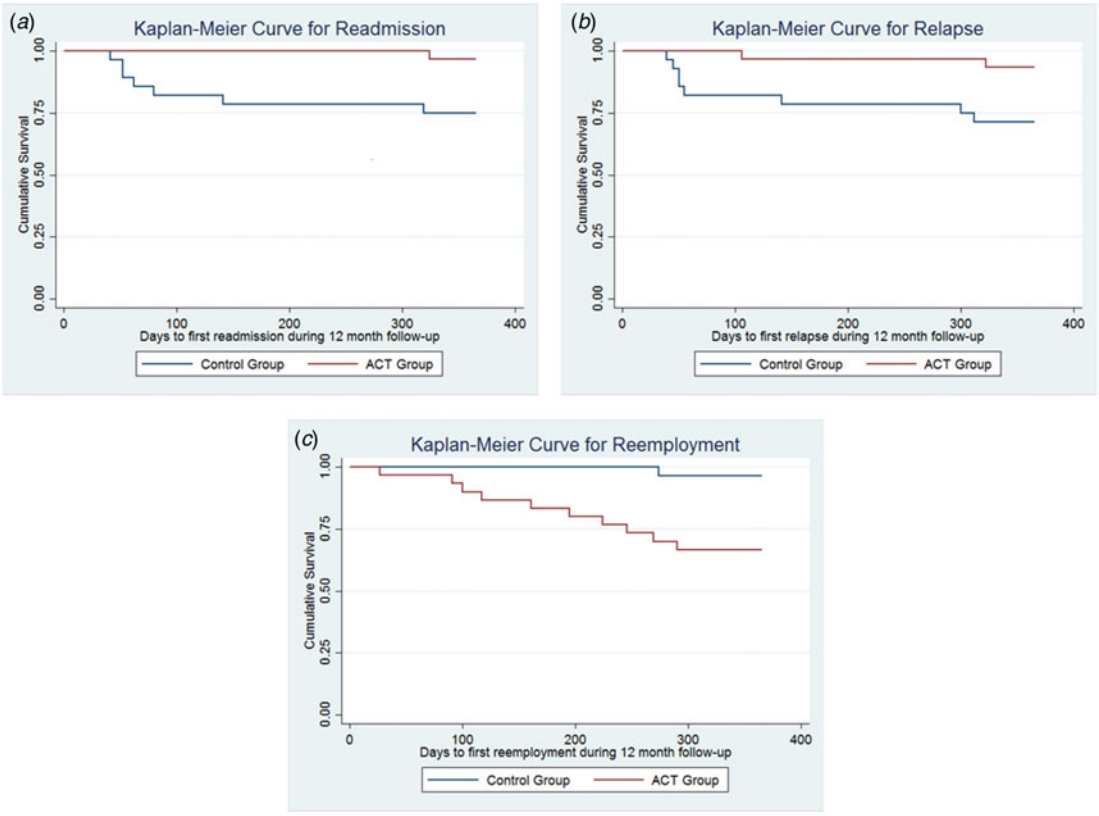

Fig. 2. Survival curves for the Assertive Community Treatment (ACT) and control (usual care) groups showing 'survival' to first (*a*) readmission, (*b*) relapse, and (*c*) reemployment during 12-month follow-up.

(total days in relapse were 105 and 963, respectively). The proportion of patients who relapsed was significantly lower in the ACT group than in the control group (6.7% *v.* 28.6%, Fisher's exact test $p = 0.038$). The mean (S.D.) day of relapse was 3.5 (14.6) in the ACT group, while it was 34.4 (70.6) days in the control group. The Kaplan–Meier survival analysis for time to first relapse (see Panel B of Fig. 2) found that the mean (S.E.) time to first relapse was significantly longer in the ACT group than in the control group [355 (8.6) *v.* 296 (23.4) days, log rank $\chi^2 = 5.09$, $p = 0.024$].

Ten patients in the ACT group and one patient in the control group returned to wage-earning employment (four patients in the ACT group got competitive employment and other six were in transitional employment) over the 12-month follow-up: total days at work in the two groups were 1436 and 84, respectively. The proportion of patients who were re-employed was significantly greater in the ACT group than in the control group (33.3% *v.* 3.6%, Fisher's exact test $p = 0.006$). The mean (S.D.) day of re-employment was 47.9 (89.1) in the ACT group, while it was 3.0 (15.9) days in the control group. The Kaplan–Meier survival analysis for time to first re-employment (see Panel C of Fig. 2) found that the mean (S.E.) time to re-employment was significantly shorter in the ACT group than in the control group [301 (18.8) *v.* 362 (3.2) days, log-rank $\chi^2 = 8.47$, $p = 0.004$].

Cox regression analysis of readmission, relapse, and re-employment

As shown in Table 3, after controlling for age, duration of illness, number of prior hospitalizations, and the baseline PANSS and SDSS total scores in a Cox regression analysis, the adjusted hazard ratio for readmission is 0.072 ($p = 0.024$), indicating that the likelihood (risk) of readmission was reduced by 92.8% in the ACT group compared with that in the control group. Similarly, the adjusted hazard ratio for relapse was 0.114 ($p = 0.014$), indicating that the likelihood of relapse was reduced by 88.6% in the ACT group compared with that in the control group, and individuals with more prior hospitalizations were more likely to relapse. The Cox regression analysis for re-employment indicated a 30-fold increase in the occurrence of re-employment in the ACT group compared with that in the control group, and patients with a longer duration of illness or with higher baseline scores of PANSS/SDSS were significantly less likely to be re-employed over the follow-up period (see detailed analyses in online Supplementary Tables S2–S4).

Clinical and social outcomes

The main results for the four clinical and social functioning scales assessed at the five assessment times (at baseline and after 3, 6, 9, and 12 months) are presented in Fig. 3. Detailed results of mixed effect model analyses are shown in online Supplementary Table S3. After controlling for the baseline scores and the baseline differences in the duration of illness, the PANSS total score and subscale scores all showed a significant intervention effect ($p = 0.001 \sim 0.016$) and a significant intervention by time interaction effect ($p = 0.001 \sim 0.049$). The CGI measure also had a significant ACT intervention effect at month 3 ($p = 0.003$), and the difference was relatively stabilized at each follow-up assessment (intervention × time interaction, $p = 0.634$).

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Table 3. Hazard ratio for readmission, relapse, and reemployment during 12-month follow-up

Variables	Readmission		Relapse		Re-employment	
	Hazard ratio	*p*	Hazard ratio	*P*	Hazard ratio	*P*
Assertive Community Treatment (ACT) group (reference: control group)	0.07	**0.024**	0.11	**0.014**	31.17	**0.014**
Duration of illness >8 years (reference: ⩽8 years)	0.88	0.888	0.66	0.616	0.13	**0.024**
Number of hospitalization >3 times (reference: ⩽3)	3.76	0.121	4.84	**0.050**	0.35	0.249
Age 26–30 years (reference: 18–25 years)	0.41	0.315	0.70	0.652	0.72	0.725
Age 31–45 years (reference: 18–25 years)	0.23	0.268	0.25	0.280	5.09	0.082
Baseline PANSS score	0.99	0.727	0.97	0.353	0.92	**0.039**
Baseline SDSS score	0.85	0.419	0.83	0.318	0.64	0.058

Significant *P* values (< 0.05) are in bold.

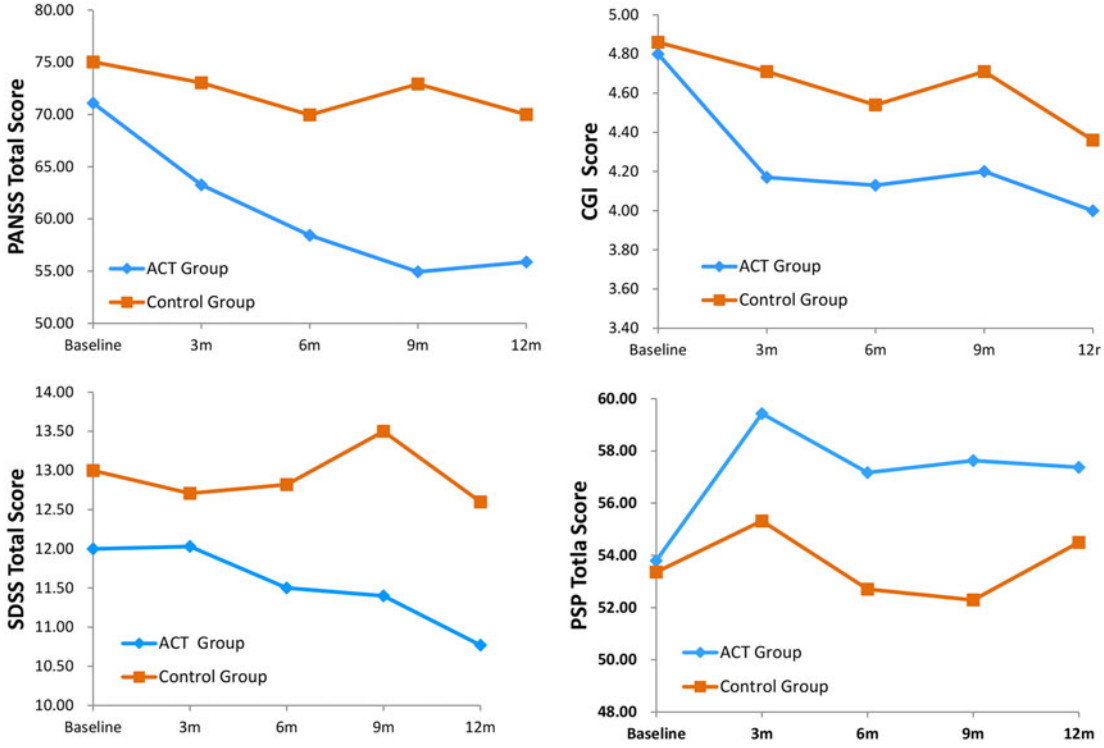

Fig. 3. Total score at baseline and 3, 6, 9, and 12 months of follow-up for the Assertive Community Treatment (ACT) and control groups of (*a*) Positive and Negative Syndrome Scale (PANSS), (*b*) Clinical Global Impression (CGI), (*c*) Personal and Social Performance Scale (PAP), and (*d*) Social Disability Screening Schedule (SDSS).

The social functioning of the patients, as measured by PSP and SDSS total scores, also showed significantly greater improvement in the ACT group than that in the control group at month 3 ($p = 0.003$; $p = 0.001$). Compared with TAU, the 1-year ACT intervention significantly decreased patients' social disability (as assessed by SDSS) at each of the follow-up, but the difference was relatively stable for social performance, as measured by PSP, at months 6, 9, and 12.

The UNIANOVA analysis of UPSA-B, FAD, and WHOQOL-BREF results are presented in online Supplementary Table S4. After controlling for baseline scores and baseline differences in the duration of illness, patients' functioning, family functioning and caregivers' quality of life all show significantly greater improvement at the time of the 1-year follow-up in the ACT group than in the control group ($p = <0.001 \sim 0.011$).

Discussion

The recent expansion of the '686 project' in China has substantially increased the availability of free community-based services for individuals with SMI (Phillips, 2013). However, given the lack of resources and well-trained mental health professionals in the community, both the coverage and quality of the services provided remain inadequate. This study, the first RCT of ACT in China, intentionally focusses on severely disabled patients who

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live in the community – those most in need of more intensive services – and assesses the relative benefit of ACT over the services currently provided by the 686 system for such patients in an urban setting. We found that ACT significantly reduced the occurrence and duration of re-hospitalization and relapse, increased the occurrence and duration of employment, and improved the clinical symptoms, daily functioning, family relationships, family functioning, and caretakers' quality of life. The results provide robust evidence that a culturally adapted ACT intervention can be both feasible and effective in urban China.

There are likely numerous factors contributing to these positive outcomes. Broadly speaking, international research shows that high fidelity ACT teams perform better, associated with the model's high service intensity, multi-discipline team approach, among other features (Winter and Calsyn, 2000). This study team's moderately high fidelity in implementing the high-intensity, multi-disciplinary ACT services likely contributed to the overall success. More unique to the study setting, the cultural adaptation of the ACT program for use in China also likely played a role in its success. In China, over 90% of individuals with SMI reside with family members; patients who receive treatment are almost always brought to care by family members; and these patients rarely have comorbid substance abuse or other dual diagnoses [even cigarette smoking is lower than in the general population (Wang *et al.*, 2010)]. The current ACT study addressed these aspects by prioritizing intensive family psycho-education and support, and directed fewer resources to substance-related issues which are more intensively covered in the west. While the western ACT model also advocates family psychoeducation and support as a form of best-practice (Buchanan *et al.*, 2010), in the current study family supports were systematically implemented and received focused attention as a core feature of ACT. This finding builds on Asian research in ACT (Sono *et al.*, 2008; Ito *et al.*, 2011; Liem and Lee, 2013; Low *et al.*, 2013; Kim *et al.*, 2015) and general psychiatric care (Chien and Wong, 2007; Chan *et al.*, 2009; Ito *et al.*, 2012) that emphasizes the centrality of family psychoeducation in a variety of mental health services. More broadly, the current study's results highlight the need to consider the role of culture in clinical practice, and points to a need to adjust measures of fidelity when assessing ACT or other holistic interventions in non-western settings.

It is difficult to isolate the specific ingredients responsible for the ACT model's general success in a wide range of settings (Bond and Drake, 2015), primarily because it is a highly structured model, with pre-determined team structure, resource and operational requirements, and personalized care philosophy, elements that cannot easily be separated from each other. The current study provides suggestive evidence that ACT's person-centered, recovery-oriented treatment practices and guiding philosophy (Salyers and Tsemberis, 2007; Salyers *et al.*, 2010), has by design affected the underlying philosophy and *nature* of care for the treatment group. This difference goes beyond the frequency and intensity of treatment contacts, or medication-based treatment. To a significant extend, the core mandate of current standard community mental health care in China (such as the '686 project') is to reduce the social and domestic disturbances caused by people with SMI, while individual recovery and quality of life issues are not prioritized (Guan *et al.*, 2015). In contrast, the study's ACT group benefitted from the individually tailored, respectful, quality of life-driven services prescribed by the model. These qualitative differences may have contributed to the positive outcomes, along with enhanced community integration and rehabilitation, and de-stigmatization of mental illness. In this sense, ACT is an embodiment of a newer attitude and approach to community care, with potentially far-reaching impact on how services could be delivered in China. Further qualitative studies to expand the understanding of this powerful new service philosophy are warranted.

Other positive contributing factors are likely interactive. The current study's findings that the ACT intervention has led to improvement of patients' levels of social functioning, employment, families' relationships, functioning, and family member's level of quality of life, may partly be the results of less severe psychopathology, as shown by the reductions in PANSS scores across several dimensions. There is a virtuous cycle where decreased interference from psychiatric symptoms contributes to patients' ability to pursue life-enhancing activities, in turn lowering the interfering effects of psychopathology.

It is notable that this study found a significant reduction of negative symptoms and improvement of social functioning, as they go beyond the typical expectation. Negative psychotic symptoms are well-known to be recalcitrant, not treatable by antipsychotic medications alone (Andreasen *et al.*, 1990; Erhart *et al.*, 2006). The current study's ACT services may have achieved success by active and frequent engagements so patients are less emotionally withdrawn than the past, improved on inter-personal rapport, and become less socially ostracized and withdrawn. The multi-disciplinary, recovery-oriented, family inclusive, and assertive outreach services of ACT model that were sustained over a period of time seem plausible a mechanism for improving negative symptoms of schizophrenia. A major European study had also shown that ACT services confer long-lasting effect on social functioning improvement, beyond the reduction in hospitalization effect (Bertelsen *et al.*, 2008). The current study's significant improvements in social functioning and reemployment show that ACT is not only able to reduce hospitalization and relapse rates in the Chinese setting, but also to improve patients' daily living standards and social functioning capacity, and is likely to reduce overall social costs of schizophrenia treatment, an area needing urgent improvement (Xiang *et al.*, 2012).

The current study also has some methodological advantages. Most research studies on ACT have outcome measures limited to the realm of relapses and re-hospitalizations (Dixon, 2000; Bond and Drake, 2015). Moreover, the use of the rate and duration of readmissions as primary outcome measures for ACT may become problematic in settings where administrative and resource changes are resulting in fewer, briefer readmissions. The current RCT study has improved on these limitations by simultaneously considering a wider array of clinical, social and familial outcome measures, and varied, informative statistical analyses. One insight was gained from the employment of survival analyses and the repeated measures analysis of the PANSS results that show patients in the ACT group were continuously clinically stable for longer periods than patients in the control group. Finally, the increased rate of gainful employment was an encouraging outcome that is not easily achieved in the SMI population which was also reported in successful studies of ACT in Europe (Bertelsen *et al.*, 2008).

Several limitations of the study should be considered. Despite the adequate power to demonstrate statistical significance, this study has a relatively small sample size and very few outcome events occurred, limiting the robustness of the results. The generalizability is therefore potentially limited by operator dependent variables. The index of relapse days is based on the retrospective

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reports of the patient and his/her family members every month, which might affect the accuracy of the estimate. The intervention was only assessed for 1 year, so it is not possible to determine whether or not the reported relative benefits over routine care would persist over longer periods, or how much further improvement may occur. Further multi-site studies with larger samples that follow-up patients longer are warranted. The rapidly changing socio-cultural environment of urban China has been associated with a gradual transition from the traditional collectivist family-centered culture to a more individualistic person-centered culture, so it is likely that the culture-specific modifications of the ACT model used in this study will need to be periodically updated as the culture in China changes. Due to the loss of contact, two participants in the control group were excluded from the analysis. If the loss of contact were partially related to the occurrence of selected outcomes, the effect on the study results would have been biased towards underestimation.

Furthermore, given the current shortages of mental health resources in China, it is not realistic to provide ACT services to all suitable patients with SMI in the country, particularly to patients living in rural communities – however desirable such an outcome may appear based on this early data. The growing policy support for community-based health care at the national level in China (Xiong and Phillips, 2016) adds to the relevance of this study: the highly effective ACT model could be added to the repertoire of strategies to selectively target the needs of severely disabled individuals whose needs are not being met by currently available programs.

Conclusion

This first RCT study in China finds that a culturally-adapted ACT program in urban China is both feasible and highly effective over a 1-year follow-up period for reducing relapses and re-hospitalizations, for increasing participants' gainful employment, and for improving care givers' quality of life. Replication of the study with larger samples that follow participants for longer periods of time are needed to determine the feasibility and potential benefits of providing this treatment to the millions of severely mentally ill individuals in this country.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0033291718001629.

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Contributors. XW designed the study and supervized the data collection and analysis. XL was the lead psychiatrist on the trial and wrote the first draft with SFL. WZ, XM, and SL provided the ACT intervention for the patients and collected the data. XL, JS, and WZ analyzed the data. MP supervised the implementation of the whole study and contributed to the revision of the final draft of the report. All other authors reviewed the results, or contributed important intellectual content.

Declaration of interests. The authors declare no competing interests.

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