# First-Episode Services for Psychotic Disorders in the U.S. Public Sector: A Pragmatic Randomized Controlled Trial

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**Objective:** This study sought to determine the effectiveness of a comprehensive first-episode service, the clinic for Specialized Treatment Early in Psychosis (STEP), in an urban U.S. community mental health center by comparing it with usual treatment.

**Methods:** This pragmatic randomized controlled trial enrolled 120 patients with first-episode psychosis within five years of illness onset and 12 weeks of antipsychotic exposure. Referrals were mostly from inpatient psychiatric units, and enrollees were randomly allocated to STEP or usual treatment. Main outcomes included hospital utilization (primary); the ability to work or attend age-appropriate schooling—or to actively seek these opportunities (vocational engagement); and general functioning. Analysis was by modified intent to treat (excluding only three who withdrew consent) for hospitalization; for other outcomes, only data for completers were analyzed.

**Results:** After one year, STEP participants had less inpatient utilization compared with those in usual treatment: no

psychiatric hospitalizations, 77% versus 56% (risk ratio [RR]=1.38, 95% confidence interval [CI]=1.08–1.58); mean hospitalizations,  $.33\pm.70$  versus  $.68\pm.92$  (p=.02); and mean bed-days,  $5.34\pm13.53$  versus  $11.51\pm15.04$  (p=.05). For every five patients allocated to STEP versus usual treatment, one additional patient avoided hospitalization over the first year (number needed to treat=5; CI=2.7–26.5). STEP participants also demonstrated better vocational engagement (91.7% versus 66.7%; RR=1.40, CI=1.18–1.48) and showed salutary trends in global functioning measures.

**Conclusions:** This trial demonstrated the feasibility and effectiveness of a U.S. public-sector model of early intervention for psychotic illnesses. Such services can also support translational research and are a relevant model for other serious mental illnesses.

Psychiatric Services 2015; 66:705-712; doi: 10.1176/appi.ps.201400236

The first few years after psychosis onset presage much of the eventual morbidity in schizophrenia spectrum disorders, including suicidality (1), functional losses related to relapse and hospitalization (2), violence (3), and the onset of other potentially modifiable prognostic factors, such as substance misuse and social isolation. Several pharmacologic and psychological interventions have been shown to improve outcomes (4) during this critical "window of opportunity" for ameliorating long-term disability (5). Of particular promise are comprehensive first-episode services (FES) with teams that integrate and adapt the delivery of empirically based treatments to younger patients and their families (6).

FES programs have received strong support in Europe, Australia, and most notably the United Kingdom, where a national implementation strategy has been in place since 2000. Policy debates outside the United States have matured from questions about efficacy (can intensive FES models work?) through effectiveness (how well do FES models work in usual settings?) to implementation models (how can improvements in trials be sustained in the real world?) (7) and health-economic analyses (8). Accumulating results validate a "best available evidence" (9) argument for funding and implementing FES models as platforms to deliver needed care while investigating their value (10) for a particular health care system.

Significant uncertainty remains, however, about the feasibility and impact of FES in the fragmented U.S. health care system, wherein deployment has required creative approaches to resourcing (11) that limit scale. Meanwhile, chronic psychotic disorders are the leading contributor to mental illness expenditures in the United States (\$62.7 billion in 2002). Much of direct health care costs are attributable to psychiatric hospitalization, but a larger proportion (64%) arises from indirect costs related to reduced vocational functioning. Demonstrating the effectiveness of a nationally relevant FES model can address the status quo.

The clinic for Specialized Treatment Early in Psychosis (STEP) was established in 2006 within a public-academic collaboration (12). The guiding question for the study reported here was, Can an FES program in the U.S. public sector meaningfully improve outcomes for individuals early

in the course of a psychotic illness? We hypothesized that STEP would be more effective than usual services as measured by the primary outcome of psychiatric hospitalization and a range of secondary measures related to community functioning, with a focus on vocational engagement. We report one-year outcomes of a pragmatic randomized controlled trial testing the effectiveness of STEP versus usual care in a real-world U.S. setting.

#### **METHODS**

#### Setting and Design

STEP is located within the Connecticut Mental Health Center (CMHC). The center serves a catchment of about 200,000 persons eligible for public-sector care in the greater New Haven area. CMHC has an average daily census of 2,500 active outpatients receiving care for a variety of serious mental illnesses, personality disorders, and substance use disorders. The Connecticut Department of Mental Health and Addiction Services (DMHAS) owns the facility and hires most of the clinical staff. DMHAS collaborates via a staffing contract with the Yale Department of Psychiatry that provides psychiatrists, psychologists, and administrative staff for the center.

A "pragmatic" randomized controlled design (13) was employed to include a broad, relevant sample; intervene within the resources of a community mental health center with an ecologically salient comparator; and collect data on clinically relevant outcomes. To test the value of FES, DMHAS in discussions with the principal investigator in 2006 agreed to waive three customary exclusions for care at CMHC. Thus patients experiencing early psychosis who were eligible for this study and who were randomly assigned to STEP care were offered services at the CMHC even if they were privately insured, lived outside the center's statutory catchment area, or were under 18 years old.

#### Sampling

The study recruited participants from April 2006 to April 2012, and all assessments were concluded in May 2013 to allow for at least one year of follow-up for all enrollees. Recruitment efforts were limited to informing local hospitals, emergency departments, and community clinics; making invited presentations to professional groups; and regularly visiting the largest regional private, nonprofit psychiatric hospital.

We included all individuals between the ages of 16 and 45 who were within five years of onset of a psychotic illness, who had not received more than 12 weeks of treatment with antipsychotic medications in their lifetime, and who were willing to travel to STEP for treatment. Minimal exclusions were as follows: patients whose psychosis was confirmed as secondary to a general medical disease, an affective disorder, or a substance use disorder; and patients with severe cognitive (IQ <70) and functional limitations that qualified them for care from the Department of Disability Services.

Informed consent was obtained from all participants per procedures of the study protocol approved by the Yale University Institutional Review Board.

#### Allocation

Eligible patients were randomly assigned to STEP or to treatment as usual by permuted and concealed random blocks between 2 and 5. The research statistician independently generated the random sequence kept in sealed envelopes. After a participant gave consent, research assessors contacted the statistician to open the next envelope and allocate the participant.

#### Interventions

STEP. The FES followed best practices and tailored interventions with established efficacy to the needs of younger patients and their families (14). Patients were allowed to choose from a menu of options that included psychotropic medications, family education, cognitive-behavioral therapy (CBT), and case management focused on brokering with existing CMHC-based services for employment support and with area colleges for educational support. Family education was delivered with combinations of multifamily group and individual family sessions. CBT principles informed group and individual approaches. Although academic psychologists initially led family and CBT groups, a train-the-trainer approach transitioned leadership to clinical staff coleaders. In keeping with the pragmatic ethos, clinician time was reallocated from existing ambulatory services. The team consisted of staff and trainees from psychiatry, psychology, social work, and nursing. Collaborative team management allowed interventions to be offered in a manner targeting patient and family needs but rested finally in patient choice. The FES implementation has been described in published protocols (15,16), and manuals are available upon request.

*Treatment as usual.* Patients randomly assigned to usual treatment either continued treatment with existing outpatient providers or were referred on the basis of health insurance coverage. For referrals to the study from inpatient units, eligibility assessment and allocation were completed before discharge to preclude any treatment disruptions, especially for those allocated to usual treatment. Given the pragmatic nature of the design, no treatment guidelines were provided to the community practitioners, but utilization by participants of the various treatments was assessed. The relatively few patients who were randomly assigned to usual treatment and who were eligible for public-sector care at CMHC (N=8) were referred per routine practice to one of the ambulatory teams at the center.

#### Assessments

Assessments were scheduled every six months. By using assessors independent of the treatment team, we minimized measurement bias, but blinding them to the intervention arm was not feasible. Commonly employed instruments assessed psychiatric diagnosis (17), symptoms (18,19), suicidality (19), substance use (20), and functioning (21,22). Duration of untreated psychosis was derived as the time in months between onset of psychosis defined by the Symptom Onset in Schizophrenia (23) scale and initiation of antipsychotic treatment.

Hospitalization outcomes were determined from structured in-person and telephone interviews of participants, family members, and referral sources, along with review of available medical records. We supplemented these sources by querying administrative data from the largest provider of inpatient services in the region, Yale Psychiatric Hospital (YPH). Employment, school, and housing status and information about general social functioning were assessed with the Social Functioning Scale (SFS) (24), and treatment utilization was assessed with the Services Utilization and Resources Form (25). We report modified U.S. Bureau of Labor Statistics vocational categories (26) as follows: employed (in a full- or part-time job, in school, or filling parental or homemaker roles), unemployed (jobless, looking for a job, available for work, or in supported employment), and not in the labor force (any lack of capability to work or less than frequent attempts at finding work as measured by the SFS). Each category was assessed over the prior week. Those who were employed or unemployed were considered "vocationally engaged."

#### Analysis

A modified intention-to-treat analysis was conducted for the primary outcome of hospitalization. After randomization, we excluded only patients who withdrew consent for study participation. Hospitalization data were obtained for all remaining 117 participants from interviews or YPH administrative records. [A recruitment flowchart is available in an online data supplement to this article.] Other measures could be collected only for participants who were available for in-person or structured phone assessments. When sixmonth data but not 12-month data were available for vocational functioning, the six-month results were carried forward. We evaluated the validity of this carry-forward assumption. For patients with complete data, those who were vocationally engaged at six months retained this status at 12 months (93%). [A table presenting results of this analysis is included in the online supplement.]

Logistic regression (for categorical measures) and linear regression (for continuous measures) were used in models that included one-year outcomes for the dependent variables of hospitalization and vocational engagement. Effects on global functioning and symptoms were assessed with analysis of covariance. We planned to include additional baseline covariates in the models when they were significantly correlated (p<.05) in the combined samples that included STEP plus usual treatment with the 12-month outcome. No variables of interest qualified for such inclusion.

#### RESULTS

#### **Recruitment Experience**

Between April 2006 and April 2012, we received 512 requests for information, of which 491 potential participants were screened by phone for eligibility. A total of 284 were excluded, including 161 (57%) for excessive length of treatment or illness duration, 53 (19%) for a nonpsychotic illness, 19 (7%) who were too young, 16 (6%) who subsequently refused further contact, 13 (5%) who were unwilling to be treated at CMHC, 12 (4%) who were subsequently unreachable, six (2%) who were on legal probation, two (1%) who moved out of the state, and two (1%) who were monolingual Spanish. Of the 207 who completed a full in-person eligibility assessment, two were deemed ineligible and 29 were provided STEP care without randomization in an initial pilot (data not included).

We were able to enroll 120 of the remaining 176 patients. After randomized allocation, one patient from each arm withdrew consent, voicing delusional concerns about study participation. In addition, one minor was withdrawn by a parent disappointed by allocation to usual treatment. Subsequent attrition of participants was equivalent in both arms. Two patients relocated out of state with their families, and another three were incarcerated for offenses committed before study entry and were unavailable for further assessments. Four additional participants were referred out of STEP after appropriate diagnostic revision (two each for bipolar disorder and borderline personality disorder), and they subsequently declined assessments.

#### Study Sample

The study recruited a diverse, young, and preponderantly male sample, with a long and variable duration of untreated psychosis (mean 10±15 months) and evidence of significant clinical distress and functional loss, comparable to samples in similar trials (27,28) (Table 1). Specifically, almost one in ten had attempted suicide; Global Assessment of Functioning and Heinrich's Quality of Life Scale scores indicated significant socio-occupational dysfunction. Almost half had a comorbid substance use disorder (excluding nicotine use), and more than a quarter met DSM-IV chronicity criteria for schizophrenia or schizoaffective disorder. Notably, more than eight of every ten patients entered treatment via an acute emergency or inpatient setting, with moderately severe psychosis symptoms and after typically brief hospitalizations (three to five days). The two groups were broadly comparable on baseline measures (Table 1).

#### **Effectiveness Outcomes**

YPH administrative data effectively supplemented information from interviews with patients and their families and from referring clinicians and medical records. Patient and caregiver reports detected the large majority of YPH hospitalizations at baseline, but only just over half of such hospitalizations during follow-up. Unfortunately, equivalent records were not available for other hospitals, and patient and caregiver report data suggested that those in the usual-treatment group were more likely to be hospitalized away from YPH during follow-up. [Tables in the online supplement present data on hospitalizations.] This is not surprising, given that those receiving STEP care were more likely to be referred to the closest hospital (that is, YPH), whereas those assigned to care elsewhere in the community would not experience this referral preference. In

TABLE 1.	Baseline	characteristics	of patien	ts randoml	v assigned to	STEP	or to	treatment	as	usual	la
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		STEP		Us	sual treatment	
Characteristic	Total N	Ν	%	Total N	Ν	%
Sociodemographic						
Age (M±SD)	60	22.4±4.5		57	22.6±5.3	
Men	60	49	82	57	46	81
Race-ethnicity						
Black	60	22	37	57	19	33
Hispanic	60	7	12	57	10	18
Caucasian	60	27	45	57	26	46
Asian	60	2	3	57	1	2
Mixed		2	3	57	1	2
Immigrant (first generation)	37	13	35	33	12	36
Years of education ( $M\pm$ SD)	60	12.76±2.00			12.68±2.00	
General functioning (M±SD score) <sup>b</sup>						
GAF	60	36.22±12.89		57	34.42±10.43	
HQLS	60	59.87±22.25		57	59.45±18.02	
SFS global score	60	114.37±22.15		57	125.05±26.35	
In an intimate relationship	59	39	66	55	35	64
Vocational status						
Vocationally engaged	60	41	68	54	36	67
Employed or in school	60	32	53	54	33	61
Unemployed, looking for job	60	9	15	54	3	6
Not in labor force	60	19	32	54	18	33
Housing						
Private home or apartment	59	57	97	57	56	98
Shelter	59	1	2	57	0	_
Supervised setting	59	Ū.	_	57	1	2
Homeless	59	1	2	57	0 0	_
	00	-	-	07	0	
Clinical	FO	10.0+16.0		47	10.0+17.0	
Duration of untreated psychosis	52	10.0±16.0		47	10.0±15.0	
(M±SD months)	57	15	26	57	10	70
Schizophrenia or schizoariective	57	12	20	57	10	52
disorder						
Comorbidity		26	4.0	50	25	45
Substance abuse or dependence	5/	26	46	59	25	45
Anxiety disorder	51	6	12	58	4	11
Prior suicide attempt ( $\geq$ 1)	60	5	8	5/	6	11
First treatment contact	6.0	0	-		0	
STEP	60	2	5	5/	2	4
Other outpatient clinic	60	6	10	5/	5	9
Emergency department or inpatient	60	52	87	5/	50	88
Hospitalization in 6 months before						
enrollment						
0	60	11	18	55	9	16
≥1	60	53		57	52	
1	60	45	75	55	41	75
2	60	4	7	55	4	7
3	60	0	_	55	1	2
Total N of hospital days	60	546		57	650	
Bed-days (M±SD)	60	9.3±8.0		57	$11.8 \pm 11.7$	
PANSS (M±SD score) <sup>c</sup>						
Positive dimension	60	20.75±6.74		57	$19.60 \pm 5.90$	
Negative dimension	60	17.82±6.42		57	17.01±5.40	
General symptoms	60	33.42±8.62		57	$33.70 \pm 8.56$	
Total (M±SD)	60	72.0±16.76		57	70.33±15.52	

<sup>a</sup> STEP, Specialized Treatment Early in Psychosis

<sup>b</sup> Possible scores on the GAF (Global Assessment of Functioning) range from 1 to 100, with higher score indicating superior functioning in a range of activities. Possible scores on the HQLS (Heinrich's Quality of Life Scale) range from 0 to 120, with lower scores indicating severe impairment of functioning. Possible scores on the SFS (Social Functioning Scale) range from 8 to 198, with higher score indicating better social functioning.

<sup>c</sup> PANSS, Positive and Negative Syndrome Scale. Possible scores on the positive and negative dimensions range from 7 to 49, with higher scores indicating worse symptoms. Possible scores for general symptoms range from 16 to 112, with higher scores indicating worse general psychopathology. Possible total scores range from 30 to 210, with higher score indicating worse overall symptomatology.

summary, although data from YPH records made our hospitalization outcomes more comprehensive, the data likely biased measurement toward more hospitalizations in the STEP group and led to a conservative estimate of the effectiveness of STEP care in reducing psychiatric hospitalization.

Patients allocated to STEP care had better outcomes on all measures of hospital utilization (Table 2). STEP care resulted in fewer total hospitalizations (20 versus 39 with usual treatment) and a lower likelihood of hospitalization (14 of 60 [23%] patients versus 25 of 57 [44%] of those in usual treatment). These data translate to a number needed to treat (NNT) of five-that is, for every five patients allocated to STEP rather than usual care, one additional patient avoided psychiatric hospitalization over the first year. This difference was not attributable to a few high utilizers of hospital care in the usualtreatment group [see table in online supplement]. When hospitalized, patients allocated to STEP care averaged more than six fewer hospital days than those in usual treatment. The STEP cohort also accounted for fewer bed-days over the year (246 versus 495 with usual treatment).

These reductions in hospital utilization were accompanied by improved vocational outcomes. Although we were able to analyze data for only the subset of patients who were available for in-person or phone assessments, about nine of every ten patients allocated to STEP care were classified as vocationally engaged at follow-up versus about six of every ten of those allocated to usual treatment (Table 2). Although at study entry patients allocated to usual treatment were more likely to be employed or in college or high school at least part-time (Table 1), this advantage reversed within one year (Table 2 and Figure 1).

STEP patients were more likely to be in contact with outpatient mental health services and showed improvements in a variety of measures of community functioning and symptoms (Table 3), consistent with their statistically more robust advantages in hospitalization and vocational engagement outcomes.

### DISCUSSION

This is the first randomized trial of an FES program in the United States. It demonstrated the effectiveness of a publicsector model of early intervention for psychotic illnesses. STEP care reduced hospital utilization and improved vocational functioning within the first year of enrollment. Almost nine of every ten patients entered the study from an acute care setting; however, more than three-quarters of STEP patients avoided hospitalization over the first year of treatment, compared with a little over half of those allocated to usual treatment. Patients in usual care were more likely to drop out of the labor force (33% versus 8% in STEP).

Several design features are relevant to the interpretation of this study. As a pragmatic trial, it retained the benefit of randomization for unknown prognostic variables while ensuring ecologic validity in the three fundamental domains of patients, interventions, and outcomes (29). First, wide inclusion criteria with minimal barriers to entry recruited a sample representative of the types of patients who usually present for care at this site. Second, the model of care was implemented within the resources of a public-sector ambulatory service and compared with a relevant alternative. Finally, outcomes of greatest pragmatic relevance to the system of care were collected over a period of meaningful duration. All of these aspects speak most directly to managers of limited health care resources who are contemplating the value of FES.

The setting of this study is key to evaluating its generalizability. CMHC is part of a nationwide network of state agencies that was established under the federal Community Mental Health Centers Act of 1963. As we have argued previously (12), these public-sector agencies were previously molded by efforts to deinstitutionalize persons with chronic illness, and they now provide an excellent national platform for early intervention. Also, although full implementation of the Affordable Care Act will expand Medicaid coverage and subsidize private coverage via health insurance marketplaces, payment and expertise for services classified as nonmedical, such as the rehabilitative services essential for FES, will likely continue to reside within these state agencies (11).

We recognize several limitations. First, the pragmatic design with broad eligibility and office-based care lowered barriers to entry but also engendered loss to treatment and follow-up in a population well known to be difficult to

		STEP		Treat	ment as usu	al	OR or		AOR or		Estimated				
	Total			Total			regression		regression		relative				
Outcome	z	Z	%	z	Z	%	coeff.	95% CI	coeff.	95% CI	risk	95% CI	NNT <sup>b</sup>	95% CI	d
Hospitalization															
Not hospitalized	60	46	77	57	32	56	2.56	1.16 - 5.68	2.73 <sup>c</sup>	1.22-6.0	1.38	1.08 - 1.58	Ŋ	2.7-26.5	.014
N of hospitalizations ( $M \pm SD$ )		.33±.70			.68±.92		.21	.05–.65	.21 <sup>d</sup>	.04–.65					.023
Bed-days (M±SD)		$5.34 \pm 13.53$			$11.51 \pm 15.04$		.21	.14–12.18	.21 <sup>e</sup>	.03-12.20					.046
/ocational status															
Vocationally engaged	48	44	92	39	26	67	5.50	1.62 - 18.64	6.60 <sup>f</sup>	1.84–23.65	1.40	1.18 - 1.48	4	2.4–12.1	.004
Employed or in school	48	35	73	39	21	54	5.41	1.56 - 18.80	7.01 <sup>f</sup>	1.83–26.74	1.50	1.21 - 1.60	4	2.1-11.0	.004
Unemployed, looking for job	48	6	19	39	5	13	5.85	1.22-27.99	$5.81^{f}$	1.21-27.95	2.52	2.14-3.37	М	1.4 - 11.2	.028
Not in labor force	48	4	ω	39	13	33									
n contact with mental health services	45	39	87	42	33	79	2.12	.46–9.64	2.76 <sup>g</sup>	.54-14.05	1.42	.77–2.59	па		.220
<sup>a</sup> STEP, Specialized Treatment Early ir <sup>2</sup> Number needed to treat	n Psychc	osis													

FABLE 2. Main outcome measures for patients randomly assigned to STEP or to treatment as usual<sup>a</sup>

Adjusted for pretreatment hospitalizations Adjusted for prior hospitalization number vocational engagement status

for baseline

Adjusted

Adjusted for

for gender and race-ethnicity prior hospitalization days

Adjusted .





<sup>a</sup> STEP, Specialized Treatment Early in Psychosis. Between-groups comparisons: for hospitalization rates (adjusted for pretreatment hospitalization), omnibus  $\chi^2$ =5.60, df=1, p=.018; for vocational engagement (adjusted for pretreatment vocational engagement), omnibus  $\chi^2$ = 9.56, df=1, p=.002

retain (30,31). The related attrition from in-person assessments, while comparable to that in other seminal trials (28), limited statistical power to resolve secondary outcomes. Although we were able to successfully recover hospitalization data from the dominant local provider, this likely biased data collection toward more hospitalization events in the STEP group. We thus expect actual effectiveness of FES in reducing psychiatric hospitalization to be greater than reported here.

Second, although this design addressed the question of whether and how much benefit was derived from an FES program compared with the actual choices patients face in usual care, it cannot resolve questions about which elements of the model were crucial to its success. STEP care was assembled from treatments with established efficacy, and treatment utilization measures were designed for health economic analysis focused on the number, provider type, and setting of health care visits; but fidelity was not assessed. Also our model of care deliberately envisioned the variety and dose of treatment components to vary with patient need and choice, which would confound any causal inferences between type of treatment received and outcome. With these caveats, there was no clear difference in choice of medications between groups; however, there was likely increased outpatient contact in STEP (27.6 versus 18.9 visits per patient for usual treatment over the first year [see table in the online supplement]). Also we suspect, but cannot prove, that the content of usual care in the community was less inclusive of family education and CBT approaches. In summary, STEP care was qualitatively and quantitatively different from usual care, but determination of which elements were pivotal to better outcomes is beyond the scope of this study design. Health economic evaluation of the

relative costs and benefits based on quantitative utilization estimates will be presented in a future report.

These results are broadly consistent with those of other studies of integrated care for early psychosis (32) but add a vital component to our knowledge base. The three seminal randomized trials of FES conducted in the United Kingdom, Denmark, and Norway (27,33,34) used communitybased teams with patient-to-clinician ratios of 10:1 to 12:1. In comparison, STEP is more generalizable to U.S. community settings, with average patient-clinician ratios of 50:1 and office-based care. Although the long history of public-academic collaboration makes CMHC a somewhat unique environment for service innovation (35), reports from Massachusetts, California, and North Carolina (36–38) support the feasibility of implementing similar publicly funded FES

TABLE 3.	Other measures of	of outcome for	or patients	randomly	assigned t	o STEP	or to	treatment	as usual <sup>a</sup>
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		Change	from baseline	9					
	ST	EP	Treatmer	nt as usual		ANG	COVA <sup>b</sup>		
Outcome	М	SD	М	SD	95% CI	F	df	Partial $\eta^2$	р
GAF <sup>c</sup>	22.22	15.46	20.38	16.61	-5.31 to 8.43	.20	1, 64	.003	.652
HQLS <sup>d</sup>	9.81	29.85	80	20.18	-5.38 to 18.11	1.17	1, 59	.020	.283
Social Functioning Scale	6.73	25.13	.72	26.20	-21.06 to 8.05	.81	1, 44	.018	.373
PANSS <sup>e</sup>									
Positive dimension	-7.52	8.50	-2.37	5.71	-7.39 to -1.65	9.94	1, 62	.138	.002
Negative dimension	-1.36	7.82	1.44	8.30	-4.36 to 2.59	.26	1, 62	.004	.612
General symptoms	-3.76	9.14	1.74	11.71	-9.57 to40	4.72	1, 62	.071	.034
Total	-13.56	16.65	.81	20.59	-18.4 to -7.07	8.01	1, 62	.116	.006

<sup>a</sup> STEP, Specialized Treatment Early in Psychosis

<sup>b</sup> Analysis of covariance. All comparisons were adjusted for baseline scores. HQLS was also adjusted for PANSS negative dimension baseline score. Social Functioning Scale was also adjusted for the duration of untreated psychosis.

<sup>c</sup> Global Assessment of Functioning

<sup>d</sup> Heinrich's Quality of Life Scale

<sup>e</sup> Positive and Negative Syndrome Scale

programs across distinct and heterogeneous U.S. health care ecologies.

#### CONCLUSIONS

This U.S. trial of a public-sector FES model extends the international literature supporting the feasibility and effectiveness of comprehensive early intervention for psychotic illnesses.

#### AUTHOR AND ARTICLE INFORMATION

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This work was supported by grants to Dr. Srihari, principal investigator, from the Donaghue Foundation (DF07-014) and the National Institutes of Health (MH088971). The trial is registered at ClinicalTrials.gov (NCT00309452).

Dr. Tek has served as a consultant for Genentech Inc. Dr. Breitborde has received research funding from Pfizer. Dr. Woods has received investigator-initiated and sponsor-initiated research funding from or has served as a consultant to Biomedisyn, Bristol-Myers Squibb, Eli Lilly and Company, Glaxo, Glytech, Hoffmann-LaRoche, Janssen, Kali-Duphar, Laxdale, Medi-Physics, Merck, Otsuka, Pfizer, Sandoz, Sanofi Synthélabo, Schering-Plough, UCB Pharma, and Zeneca. He has been granted a U.S. patent for a method of treating prodromal schizophrenia with glycine agonists and has a patent pending for a method of predicting psychosis risk using blood biomarker analysis. The other authors report no financial relationships with commercial interests.

Received May 29, 2014; revision received September 6, 2014; accepted September 15, 2014.

#### REFERENCES

- Westermeyer JF, Harrow M, Marengo JT: Risk for suicide in schizophrenia and other psychotic and nonpsychotic disorders. Journal of Nervous and Mental Disease 179:259–266, 1991
- Robinson DG, Woerner MG, McMeniman M, et al: Symptomatic and functional recovery from a first episode of schizophrenia or schizoaffective disorder. American Journal of Psychiatry 161:473–479, 2004
- 3. Large MMM, Nielssen O: Violence in first-episode psychosis: a systematic review and meta-analysis. Schizophrenia Research 125:209–220, 2011
- 4. Marshall M, Rathbone J: Early intervention for psychosis. Cochrane Database of Systematic Reviews 6:CD004718, 2011
- Birchwood M, Todd P, Jackson C: Early intervention in psychosis: the critical period hypothesis. British Journal of Psychiatry Supplement 172:53–59, 1998
- Srihari VH, Shah J, Keshavan MS: Is early intervention for psychosis feasible and effective? Psychiatric Clinics of North America 35:613–631, 2012
- Birchwood M, Lester H, McCarthy L, et al: The UK national evaluation of the development and impact of Early Intervention Services (the National EDEN studies): study rationale, design and baseline characteristics. Early Intervention in Psychiatry 8:59–67, 2014

- Mihalopoulos C, Harris M, Henry L, et al: Is early intervention in psychosis cost-effective over the long term? Schizophrenia Bulletin 35:909–918, 2009
- 9. McGorry P: At issue: Cochrane, early intervention, and mental health reform: analysis, paralysis, or evidence-informed progress? Schizophrenia Bulletin 38:221–224, 2012
- Porter ME: What is value in health care? New England Journal of Medicine 363:2477–2481, 2010
- Goldman HH, Karakus M, Frey W, et al: Financing first-episode psychosis services in the United States. Psychiatric Services 64: 506–508, 2013
- Srihari VH, Breitborde NJK, Pollard J, et al: Early intervention for psychotic disorders in a community mental health center. Psychiatric Services 60:1426–1428, 2009
- 13. Hotopf M: The pragmatic randomised controlled trial. Advances in Psychiatric Treatment 8:326–333, 2002
- 14. Edwards J, McGorry JE: Implementing Early Intervention in Psychosis. London, Martin Dunitz, 2002
- Breitborde NJK, Srihari VH: Family work for first-episode psychosis: a service delivery protocol; in Psychosis: Causes, Diagnosis and Treatment. Edited by Anastassiou-Hadjicharalambous X. New York, Nova Science Publishers, 2011
- Saksa JR, Cohen SJ, Srihari VH, et al: Cognitive behavior therapy for early psychosis: a comprehensive review of individual vs group treatment studies. International Journal of Group Psychotherapy 59:357–383, 2009
- First MB, Spitzer RL, Gibbon M, et al: Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Patient Edition (SCID-I/P). New York, New York State Psychiatric Institute, Biometrics Research, 2002
- Kay SR, Fiszbein A, Opler LA: The Positive and Negative Syndrome Scale (PANSS) for schizophrenia. Schizophrenia Bulletin 13:261–276, 1987
- Addington D, Addington J, Maticka-Tyndale E: Assessing depression in schizophrenia: the Calgary Depression Scale. British Journal of Psychiatry Supplement 163(suppl 22):39–44, 1993
- Drake RE, Rosenberg SD, Mueser KT: Assessing substance use disorder in persons with severe mental illness. New Directions for Mental Health Services 1996:3–17, 1996
- Heinrichs DW, Hanlon TE, Carpenter WT Jr: The Quality of Life Scale: an instrument for rating the schizophrenic deficit syndrome. Schizophrenia Bulletin 10:388–398, 1984
- 22. Hall RC: Global Assessment of Functioning: a modified scale. Psychosomatics 36:267-275, 1995
- 23. Perkins DOD, Leserman J, Jarskog LFL, et al: Characterizing and dating the onset of symptoms in psychotic illness: the Symptom Onset in Schizophrenia (SOS) inventory. Schizophrenia Research 44:1–10, 2000
- 24. Birchwood M, Smith J, Cochrane R, et al: The Social Functioning Scale: the development and validation of a new scale of social adjustment for use in family intervention programmes with schizophrenic patients. British Journal of Psychiatry 157:853–859, 1990
- 25. Rosenheck RA, Lieberman JA: Cost-effectiveness measures, methods, and policy implications from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) for schizophrenia. Journal of Clinical Psychiatry 68:e05, 2007
- How the Government Measures Unemployment. Washington, DC, Bureau of Labor Statistics, 2014. Available at www.bls.gov/cps/ cps\_htgm.htm
- 27. Craig TKJ, Garety P, Power P, et al: The Lambeth Early Onset (LEO) Team: randomised controlled trial of the effectiveness of specialised care for early psychosis. BMJ (Epub Oct, 14, 2004)
- Petersen L, Nordentoft M, Jeppesen P, et al: Improving 1-year outcome in first-episode psychosis: OPUS trial. British Journal of Psychiatry Supplement 48:s98–s103, 2005
- 29. Hotopf M, Churchill R, Lewis G: Pragmatic randomised controlled trials in psychiatry. British Journal of Psychiatry 175:217–223, 1999

- 30. Kreyenbuhl J, Nossel IR, Dixon LB: Disengagement from mental health treatment among individuals with schizophrenia and strategies for facilitating connections to care: a review of the literature. Schizophrenia Bulletin 35:696–703, 2009
- Doyle R, Turner N, Fanning F, et al: First-episode psychosis and disengagement from treatment: a systematic review. Psychiatric Services 65:603-611, 2014
- 32. Marshall M, Rathbone J: Early intervention for psychosis. Schizophrenia Bulletin 37:1111–1114, 2011
- 33. Petersen L, Jeppesen P, Thorup A, et al: A randomised multicentre trial of integrated versus standard treatment for patients with a first episode of psychotic illness. BMJ 331:602, 2005
- 34. Grawe RW, Falloon IRH, Widen JH, et al: Two years of continued early treatment for recent-onset schizophrenia:

a randomised controlled study. Acta Psychiatrica Scandinavica 114: 328–336, 2006

- 35. Jacobs S, Griffith EEH: 40 Years of Academic Public Psychiatry. London, Wiley, 2007
- 36. Caplan B, Zimmet SV, Meyer EC, et al: Prevention and recovery in early psychosis (PREP): building a public-academic partnership program in Massachusetts, United States. Asian Journal of Psychiatry 6:171–177, 2013
- Hardy KV, Moore M, Rose D, et al: Filling the implementation gap: a community-academic partnership approach to early intervention in psychosis. Early Intervention in Psychiatry 5:366–374, 2011
- Uzenoff SR, Penn DL, Graham KA, et al: Evaluation of a multielement treatment center for early psychosis in the United States. Social Psychiatry and Psychiatric Epidemiology 47:1607–1615, 2012

## Submissions Invited for Column on Integrated Care

The integration of primary care and behavioral health care is a growing research and policy focus. Many people with mental and substance use disorders die decades earlier than other Americans, mostly from preventable chronic medical illnesses. In addition, primary care settings are now the gateway to treatment for behavioral disorders, and primary care providers need to provide screening, treatment, and referral for patients with general medical and behavioral health needs.

To stimulate research and discussion in this critical area, *Psychiatric Services* has launched a column on integrated care. The column focuses on services delivery and policy issues encountered on the general medical–psychiatric interface. Submissions are welcomed on topics related to the identification and treatment of (a) common mental disorders in primary care settings in the public and private sectors and (b) general medical problems in public mental health settings. Reviews of policy issues related to the care of comorbid general medical and psychiatric conditions are also welcomed, as are descriptions of current integration efforts at the local, state, or federal level. Submissions that address care integration in settings outside the United States are also encouraged.

Benjamin G. Druss, M.D., M.P.H., is the editor of the Integrated Care column. Prospective authors should contact Dr. Druss to discuss possible submissions (bdruss@emory.edu). Column submissions, including a 100-word abstract and references, should be no more than 2,400 words.