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

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Abstract

Objective—This study seeks to determine the effectiveness of a comprehensive first-episode service (the clinic for Specialized Treatment Early in Psychosis, STEP) based in an urban U.S. community mental health center, compared to treatment as usual.

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Methods—This pragmatic randomized controlled trial enrolled 120 ‘first-episode psychosis’ patients within 5 years of illness onset and 12 weeks of antipsychotic exposure. Referrals were mostly from area inpatient psychiatric units and enrollees were randomly allocated to STEP or referral to routine care (TU). Main outcomes included hospital utilization (primary), ability to work, attend age-appropriate schooling or actively seek these opportunities (‘vocational engagement’), and general functioning. Analysis was by modified intent to treat (excluding only 3 who withdrew consent) for hospitalization and completers for other outcomes.

Results—After one year, STEP effected reductions on all measures of inpatient utilization vs. usual treatment: not psychiatrically hospitalized (77% vs. 56%, RR 1.38, 95% confidence interval (CI) 1.08–1.58); mean hospitalizations (0.33 ± 0.70 vs. 0.68 ± 0.92 , $p=0.02$) and mean bed days (5.34 ± 13.53 vs. 11.51 ± 15.04 , $p=0.05$). For every 5 patients allocated in STEP vs. usual treatment, one additional patient avoided psychiatric hospitalization over the first year (NNT = 5, CI 2.7–26.5). STEP also delivered better vocational engagement (91.7% vs. 66.7%, RR 1.40, 95% CI 1.18–1.48) and salutary trends in measures of global functioning.

Conclusions—This trial demonstrates 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.

Trial registration—www.ClinicalTrials.gov: NCT00309452.

Introduction

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 including substance misuse and social isolation. Several pharmacologic and psychological interventions have improved 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 has received strong support in Europe, Australia and most notably the U.K., where a national implementation strategy has been in place since 2000. Policy debates outside the U.S. have matured from questions about efficacy (can intensive FES models work?) through effectiveness (how well does FES work in usual settings?) to implementation models (how can improvements in trials be sustained in the real world?) (7), and health economic analyses (8). The resulting database validates a “best available evidence” (9) argument to resource FES as platforms to deliver needed care while investigating their value (10) for a particular healthcare system.

Significant uncertainty remains however, about the feasibility and impact of FES in the fragmented U.S. healthcare system wherein deployment has required creative approaches to resourcing(11) that limit scale. Meanwhile, chronic psychotic disorders lead mental illness expenditure in the U.S. (\$62.7 billion in 2002). Much of direct healthcare costs are due to psychiatric hospitalization, but the larger proportion (64%) arise from indirect costs related

to reduced vocational functioning. Demonstrating the effectiveness of a nationally relevant model of FES 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 this study was: can a FES 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 1-year outcomes of a pragmatic randomized controlled trial testing the effectiveness of STEP versus usual care in a recognizable U.S. setting.

Methods

Setting & 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 (a) include a broad, relevant sample, (b) intervene within the resources of a recognizable setting with an ecologically salient comparator and (c) collect clinically relevant outcomes. In order 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 early psychosis patients eligible for this study and randomized to STEP care were offered services at the Center even if they were privately insured, lived outside the center's statutory catchment, or were under 18 years of age.

Sampling

The study recruited from April 2006 to April 2012 and all assessments were concluded in May 2013 to allow for at least one year of follow-up on all enrollees. Recruitment efforts were limited to informing local hospitals, emergency rooms and community clinics, invited presentations to professional groups and regular visits to the largest regional private, non-profit psychiatric hospital.

We included all individuals between the ages of 16–45 who were within 5 years of onset of a psychotic illness, within 12 weeks of lifetime antipsychotic treatment and willing to travel to STEP for treatment. Minimal exclusions were for psychoses confirmed as secondary to medical disease, affective disorder or substance use; or severe cognitive (IQ<70) and functional limitations that qualified patients for care from the Department of Disability Services.

Informed consent was obtained from all subjects per procedures of the Yale University Institutional Review Board.

Allocation

Eligible patients were randomized to STEP or 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 gaining consent, research assessors contacted the statistician to open the next envelope and allocate the subject.

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 prescription, family education, cognitive behavioral therapy, 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 multi-family group and individual family sessions. Cognitive behavioral therapy (CBT) principles informed group and individual approaches. While academic psychologists initially led family and CBT groups, a train the trainer approach transitioned leadership to clinical staff co-leaders. 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 need 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 randomized to usual treatment either continued treatment with existing outpatient providers or were referred based on health insurance coverage. For referrals to the study from inpatient units, eligibility assessment and allocation was completed prior to 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 subjects of the various treatments was assessed. The relatively few patients randomized to usual treatment 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 6 months. By using assessors independent of the treatment team, we minimized measurement bias, but blinding them to intervention arm was not feasible. Commonly employed instruments assessed psychiatric diagnosis (17), symptoms (18,19), suicidality (19), substance use (20), and functioning (21,22), (see Table 1). Duration of Untreated Psychosis (DUP) was derived as the time in months between onset

of psychosis defined by the Symptom Onset in Schizophrenia (SOS) (23) scale and initiation of antipsychotic treatment.

Hospitalization outcomes were determined from structured in-person and telephone interviews of subjects, family and referral sources along with review of available medical records. We supplemented this by querying administrative data from the largest provider of inpatient services in the region (Yale Psychiatric Hospital, YPH). Employment, school and housing status as well as general social functioning were assessed with the Social Functioning Scale (SFS) (24) and treatment utilization with the Services Utilization and Resources Form (25). We report modified U.S. Bureau of Labor Statistics (BLS) vocational categories (26) of: *Employed* (in full- or part-time jobs, school, or parental/homemaker roles), *Unemployed* (jobless, looking for jobs, and 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 on the SFS), each 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. We excluded, after randomization, only those patients who withdrew consent for study participation (Figure S1). Hospitalization data was obtained for all remaining 117 subjects from interviews or YPH administrative records. Other measures could only be collected on those subjects available for in-person or structured phone assessments. When 6-month data but not 12-month data were available for vocational functioning, the 6-month results were carried forward. We evaluated the validity of this carry-forward assumption. When data were complete, patients who were vocationally engaged at 6-months retained this status at 12 months (38/41 or 93%, Table S4).

Logistic regression (for categorical) and linear regression (for continuous measures) was 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 (Table 3). We planned to include additional baseline covariates in the models when they correlated in the combined STEP+ usual treatment samples with the 12-month outcome at $p < 0.05$. No variables in Table 1 qualified for such inclusion.

Results

Recruitment experience

Between April 2006 and April 2012 we received 512 requests for information, of which 491 were screened by phone for eligibility. 284 were excluded, including 161 (57%) due to excessive length of treatment or illness duration; 53 (19%) for a non-psychotic illness and 25 (9%) who subsequently refused further contact. Of the 207 who completed a full in-person eligibility assessment, 2 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 (Figure S1). After randomized allocation, one patient from each arm withdrew consent, voicing delusional concerns about study participation. Additionally, one minor was withdrawn by a parent disappointed by allocation to usual treatment. Subsequent attrition of subjects was equivalent in both arms. 2 patients relocated out of state with their families, while another 3 were incarcerated for offenses committed prior to study entry and were unavailable for further assessments. 4 additional subjects were referred out of STEP after appropriate diagnostic revision (2 each for bipolar disorder and borderline personality disorder) and 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 similar trials (27,28) (Table 1). Specifically, almost one in ten had attempted suicide, with GAF and HQLS scores indicating significant socio-occupational dysfunction. Almost half had a co-morbid substance use disorder (excluding nicotine use), and more than a quarter of entrants already met chronicity criteria for DSM IV schizophrenia or schizoaffective disorder. Notably, more than 8 of every 10 patients entered treatment via an acute emergency or inpatient setting, with moderately severe psychosis symptoms and typically after brief (3–5day) hospitalizations.

The two groups were broadly comparable on baseline measures (Table 1).

Effectiveness outcomes

YPH administrative data effectively supplemented interviews of patients, their families, 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 (Table S1). Unfortunately, equivalent records were not available for other hospitals, and patient and caregiver report data suggest that those in the usual treatment group were more likely to be hospitalized away from YPH during follow-up (Table S2). This is not surprising, given that those receiving STEP care were more likely to be referred to the closest hospital (i.e. YPH), while those assigned to care elsewhere in the community would not experience this referral preference. In summary, while YPH records made our hospitalization outcomes more comprehensive, it 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 enjoyed better outcomes on all measures of hospital utilization (Table 2). STEP care resulted in fewer total hospitalizations (20 vs. 39 with usual treatment) and a lower likelihood of hospitalization [$14/60$ (23%) vs. $25/57$ (44%)] with usual treatment. The latter translates to a number needed to treat (NNT) of 5 i.e.: for every 5 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 usual treatment group (Table S3). When hospitalized, patients

allocated to STEP care averaged more than 6 fewer hospital days vs. usual treatment. The STEP treated cohort also accounted for fewer bed days over the year (246 vs. 495).

These reductions in hospital utilization were accompanied by improved vocational outcomes. While we were only able to analyze the subset of patients available for in-person or phone assessments, about 9 of every 10 patients allocated to STEP care were classified as vocationally engaged at follow-up vs. about two-thirds of those allocated to usual treatment (Table 2). While usual treatment patients entered the study with a greater proportion employed or in at least part-time college or high school (Table 1), this advantage reversed within one year (Table 2 and Figure 2).

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.

Discussion

This is the first randomized trial of a first-episode service (FES) in the U.S. and demonstrates the effectiveness of a public sector model of early intervention for psychotic illnesses. STEP care reduced hospital utilization and improved vocational functioning within the first year of enrollment. While almost 9 of every 10 patients entered the study from an acute care setting, more than three-quarters of STEP patients avoided hospitalization over the first year of treatment compared to 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% vs. 8% in STEP).

Several design features are relevant to the interpretation of this study. As a pragmatic trial, it retains the benefit of randomization for unknown prognostic variables while ensuring ecologic validity in the 3 fundamental domains of patients, interventions and outcomes (29). First, wide inclusion criteria with minimal barriers to entry recruited a sample that reflects the kinds 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 to a relevant alternative. Finally, outcomes of greatest pragmatic relevance to the system of care were collected over a meaningful duration. All of these aspects speak most directly to managers of limited healthcare 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, established under the federal Community Mental Health Centers Act of 1963. As we have argued previously (12), these public sector agencies previously molded by efforts to deinstitutionalize the chronically ill, now provide an excellent national platform for early intervention. Also, while 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 non-medical, 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 retain(30,31). The related attrition from in-person assessments, while comparable to other seminal trials (28), limited statistical power to resolve secondary outcomes. While 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, while this design addresses the question of whether and how much benefit was derived from an FES in comparison to 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 healthcare visits, but did not assess fidelity. Also our model of care deliberately envisioned the variety and dose of treatments 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, but likely increased outpatient contact in STEP (27.6 vs. 18.9 visits per patient for usual treatment, Table S5) over the first year. Also we suspect, but cannot prove, that the content of usual care in the community was less enriched by structured family education and CBT approaches. In summary, STEP was likely 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 reported in a future paper.

These results are broadly consistent with other studies of integrated care for early psychosis (32) but add a vital component to our knowledge base. The 3 seminal randomized trials of FES conducted in the U.K., Denmark and Norway (27,33,34), used community-based teams with 10 to 12:1 patient to clinician ratios. In comparison, STEP is more generalizable to U.S. community settings, with average patient: clinician ratios of 50:1 and office-based care. While 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 across distinct and heterogeneous U.S. healthcare ecologies.

Conclusions

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

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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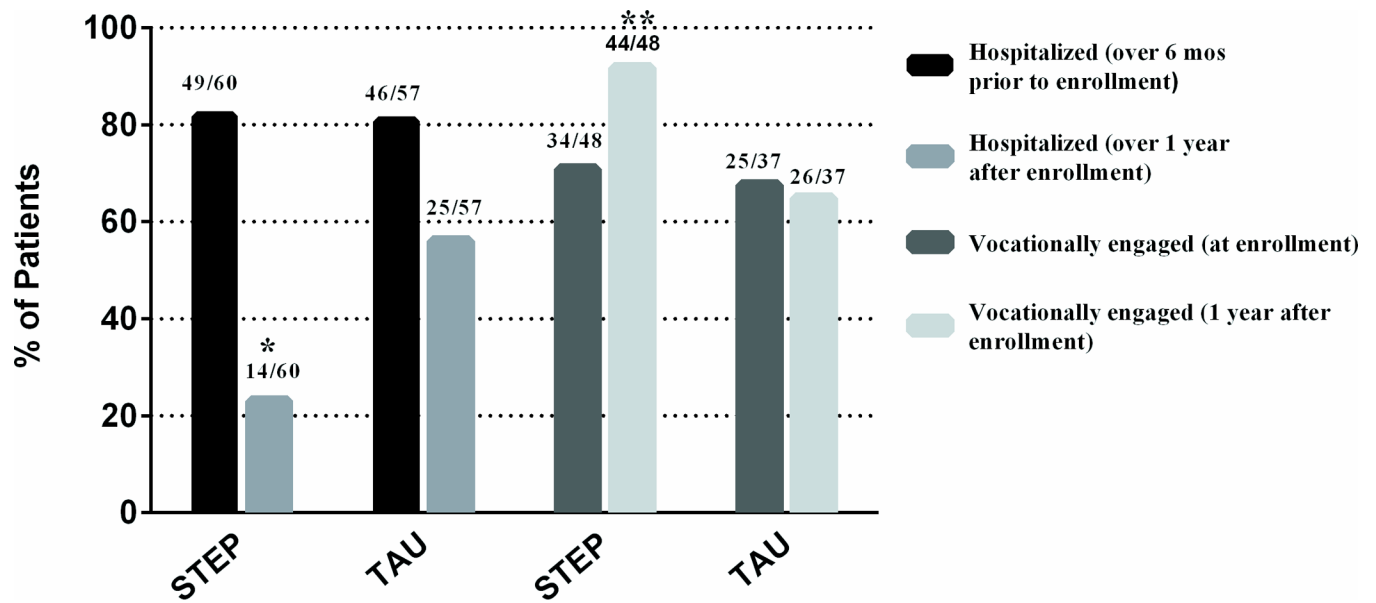


Fig. 1.
 One-year Hospitalization and Vocational Engagement outcomes of STEP vs. TU
 * Between groups comparison for hospitalization rates, adjusted for pretreatment hospitalization (Omnibus Chi-square=5.60, p=0.018)
 ** Between groups comparison for vocational engagement, adjusted for pretreatment vocational engagement (Omnibus Chi-square=9.56, p=0.002)

Table 1

Baseline characteristics of patients randomized to STEP care or treatment as usual. Values are numbers (percentages) unless stated otherwise.

	STEP			Usual treatment		
	Total N	N	%	Total N	N	%
Socio-demographic characteristics						
Age (M \pm SD)	60	22.4 \pm 4.5		57	22.6 \pm 5.3	
Men	60	49	82	57	46	81
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 gen)	37	13	35	33	12	36
Years of education (M \pm SD)	60	12.76 \pm 2			12.68 \pm 2	
General functioning						
GAF (M \pm SD)	60	36.22 \pm 12.89		57	34.42 \pm 10.43	
HQL-S (M \pm SD)	60	59.87 \pm 22.25		57	59.45 \pm 18.02	
SFS Global Score (M \pm SD)	60	114.37 \pm 22.15		57	125.05 \pm 26.35	
In an intimate relationship	59	39	66	55	35	64
Vocational status						
Vocationally engaged	60	41	68.3	54	36	66.7
Employed/In school	60	32	53.3	54	33	61.1
Unemployed, looking for job	60	9	15.0	54	3	5.6
Not in the Labor Force	60	19	31.7	54	18	33.3
Housing						
Private home/apartment	59	57	96.8	57	56	98
Shelter	59	1	1.6	57	0	0
Supervised setting	59	0	0	57	1	2
Homeless	59	1	1.6	57	0	0
Clinical Status						

	STEP			Usual treatment		
	Total N	N	%	Total N	N	%
DUP in months (M±SD)	52	10.0±16.0		47	10.0±13.0	
Schizophrenia or Schizoaffective d/o	57	15	26	57	18	32
Co-morbidity						
Substance abuse/dependence	57	26	46	59	25	45
Anxiety disorder	51	6	12	38	4	11
Prior suicide attempt (at least once)	60	5	8	57	6	11
First treatment contact						
STEP	60	2	3	57	2	4
Other outpatient clinic	60	6	10	57	5	9
ER/Inpatient	60	52	87	57	50	88
Hospitalizations in 6mos prior to enrollment						
Total number of hospitalizations	60	53		57	52	
Total number of hospital days	60	546		57	650	
Bed days (M±SD)	60	9.3±8		57	11.8±11.7	
Not hospitalized	60	11	18	55	9	16
1 time	60	45	75	55	41	75
2 times	60	4	7	55	4	7
3 times	60	0	0	55	1	2
PANSS						
Positive dimension (M±SD)	60	20.75±6.74		57	19.60±5.90	
Negative dimension (M±SD)	60	17.82±6.42		57	17.01±5.40	
General symptoms (M±SD)	60	33.42±8.62		57	33.70±8.56	
Total (M±SD)	60	72.0±16.76		57	70.33±15.52	

DUP: Duration of untreated psychosis; GAF - Global Assessment of Functioning; Scores range from 1 to 100, with higher score indicating superior functioning in a range of activities; PANNS: Positive & Negative Symptom Scale for Schizophrenia - Positive dimension ranges from 7 to 49, with higher score indicating worsening in positive symptoms, Negative dimension ranges from 7 to 49, with higher scores indicating worsening in negative symptoms, General dimension ranges from 16 to 112, with higher score indicating worsening in general psychopathology, and Total score ranges from 30 to 210, with higher score indicating worsening in overall symptomatology; HQLS - Heinrich's Quality of Life Scale; Scores range from 0 to 120, with lower scores indicating severe impairment of functioning; SFS - Social Functioning Scale Scores range from 8 to 198, with higher score indicating better social functioning.

Table 2

Main outcome measures. Values are numbers (percentages) unless stated otherwise.

	STEP		Treatment as usual				Odds Ratio/ Regression coefficient	95% CI	Adjusted Odds Ratio/Regression coefficient	95% CI	Estimated Relative Risk	95% CI	NNT	95% CI	P
	Total N	N	%	Total N	N	%									
Hospitalization															
Not hospitalized	60	46	77	57	32	56	2.56	1.16– 5.68	2.73 ^a	1.22– 6.0	1.38	1.08– 1.58	5	2.7– 26.5	.014
Hospitalization number (M±SD)		.33±.70			.68±.92		.21	.05– .65	.21 ^b	.04– .65					.023
Bed days (M±SD)		5.34±13.53			11.51±15.04		.21	.14– 12.18	.21 ^c	.03– 12.20					.046
Vocational status															
Vocationally engaged	48	44	91.7	39	26	66.7	5.50	1.62– 18.64	6.60 ^d	1.84–23.65	1.40	1.18– 1.48	4	2.4– 12.1	.004
Employed/In school	48	35	72.9	39	21	53.8	5.41	1.56– 18.80	7.01 ^d	1.83–26.74	1.50	1.21– 1.60	4	2.1– 11.0	.004
Unemployed, looking for job	48	9	18.8	39	5	12.8	5.85	1.22– 27.99	5.81 ^d	1.21– 27.95	2.52	2.14– 3.37	3	1.4– 11.2	.028
Not in the Labor Force	48	4	8.3	39	13	33.3									
In contact with mental health services															
	45	39	86.7	42	33	78.6	2.12	.46– 9.64	2.76 ^e	.54– 14.05	1.42	.77– 2.59	n/a		.220

NNT: Number Needed to Treat

^a Adjusted for past hospitalizations

^b Adjusted for prior hospitalization number

^c Adjusted for prior hospitalization days

^d Adjusted for baseline vocational engagement status

^e Adjusted for gender and ethnicity

Table 3

Other measures of outcome

	STEP		Treatment as usual				ANCOVA ^a			
	Change from baseline		Change from baseline							
	M	SD	M	SD	95% CI	F	df	Partial η^2	p	
GAF	22.22	15.46	20.38	16.61	-5.31 to 8.43	.20	1, 64	.003	.652	
HQLS ^b	9.81	29.85	-.80	20.18	-5.38 to 18.11	1.17	1, 59	.020	.283	
Social Functioning Scale ^c	6.73	25.13	.72	26.20	-21.06 to 8.05	.81	1, 44	.018	.373	
PANSS										
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 to -.40	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	

GAF: Global Assessment of Functioning; PANSS: Positive & Negative Symptom Scale; HQLS: Heinrich's Quality of Life Scale

^a All comparisons were adjusted for baseline scores and^b PANSS Negative Dimension baseline score^c Duration of Untreated Psychosis