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Supported employment and education in comprehensive, integrated care for first episode psychosis: Effects on work, school, and disability income

Robert Rosenheck [a,*], Kim T. Mueser [b,c], Kyaw Sint [a], Haiqun Lin [a], David W. Lynde [c], Shirley M. Glynn [d], Delbert G. Robinson [e,f,g], Nina R. Schooler [e,g], Patricia Marcy [e], Somaia Mohamed [a], John M. Kane [e,f,g,h]

[a] Yale Medical School, New Haven, CT, USA
[b] Center for Psychiatric Rehabilitation, Departments of Occupational Therapy, Psychiatry, and Psychology, Boston University, Boston, MA, USA
[c] Geisel School of Medicine at Dartmouth, Department of Psychiatry, Lebanon, NH, USA
[d] Semel Institute for Neuroscience and Brain Behavior, University of California Los Angeles, Los Angeles, CA, USA
[e] Zucker Hillside Hospital, Psychiatry Research, North Shore, Long Island Jewish Glen Oaks, NY, USA
[f] The Feinstein Institute for Medical Research, Manhasset, NY, USA
[g] Hofstra North Shore LIJ School of Medicine, Departments of Psychiatry and Molecular Medicine, Hempstead, NY, USA
[h] Albert Einstein College of Medicine, Department of Psychiatry and Behavioral Sciences, Bronx, NY, USA

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ABSTRACT

Background: Participation in work and school are central objectives for first episode psychosis (FEP) programs, but evidence effectiveness has been mixed in studies not focused exclusively on supported employment and education (SEE). Requirements for current motivation to work or go to school limit the generalizability of such studies.

Methods: FEP participants ($N = 404$) at thirty-four community treatment clinics participated in a cluster randomized trial that compared usual Community Care (CC) to NAVIGATE, a comprehensive, team-based treatment program that included ≥5 h of SEE services per week, , grounded in many of the principles of the Individual Placement and Support model of supported employment combined with supported education services. All study participants were offered SEE regardless of their initial interest in work or school. Monthly assessments over 24 months recorded days of employment and attendance at school, days of participation in SEE, and both employment and public support income (including disability income). General Estimation Equation models were used to compare CC and NAVIGATE on work and school participation, employment and public support income, and the mediating effect of receiving ≥3 SEE visits on these outcomes.

Results: NAVIGATE treatment was associated with a greater increase in participation in work or school ($p = 0.0486$) and this difference appeared to be mediated by SEE. No group differences were observed in earnings or public support payments.

Conclusion: A comprehensive, team-based FEP treatment approach was associated with greater improvement in work or school participation, and this effect appears to be mediated, in part, by participation in SEE.

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1. Introduction

Recent research suggests that specialized treatment programs for first episode psychosis (FEP) can improve clinical and functional outcomes in early phase schizophrenia (Bird et al., 2010; Craig et al., 2004; McGorry et al., 2010; Petersen et al., 2005). Two cluster-randomized trials demonstrate the generalizability of such programs to routine service settings (Kane et al., 2015a; Ruggeri et al., 2015). A major goal of specialized early intervention is rapid restoration of FEP patients' instrumental role functioning, particularly competitive employment or participation in school, with the hope that rapid engagement can improve functioning and prevent disability.

Evidence regarding the impact of early intervention programs on work and school outcomes has been mixed. The most comprehensive review (Bond et al., 2015) identified eleven early psychosis studies, including three randomized controlled trials (RCTs), that tested specific supported employment and education (SEE) interventions, largely based on the Individual Placement and Support (IPS) model (Drake et al., 2012). Meta-analysis of the three IPS studies found a cumulative employment rate of 49% among participants in SEE compared to only 29% among controls ($p < 0.0001$), and a greater differential increase in employment from baseline, of 41% among those in SEE compared to only

* Corresponding author at: VA New England Mental Illness Research, Education and Clinical Center, VA Connecticut Health Care System, Professor of Psychiatry and Epidemiology and Public Health, Yale Medical School, 950 Campbell Ave., West Haven, CT 06516, USA.
E-mail address: Robert.Rosenheck@Yale.Edu (R. Rosenheck).

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17% among controls ($p < 0.0001$). No significant differences were observed in school participation between SEE and comparison groups.

Bond and colleagues' (Bond et al., 2015) identified only one RCT of a vocational intervention other than IPS, which also reported significant benefits in work-school involvement (Garety et al., 2006). Five other RCTs evaluated the effectiveness of FEP programs that lacked a specific vocational component. Compared to control groups, two of these programs had better work outcomes (Eack et al., 2011; Penn et al., 2011), one program had higher rates of work or school involvement (Bertelsen et al., 2008), and two programs showed no significant differences (Bechdolf et al., 2007; Fowler et al., 2009).

A more recently published RCT compared usual services to an experimental FEP program that brokered existing clinic-based services for employment support as well as educational assistance available through area colleges (Srihari et al., 2015). Participants in the experimental intervention showed a significant increase in work or school participation from baseline to one year, while work/school involvement declined for those in usual care.

An important difference among FEP studies reviewed here is that the three RCTs examining the efficacy of IPS-SEE restricted entry to persons with stated goals of obtaining employment or going to school, whereas the studies of broader interventions included all eligible participants with FEP, regardless of personal vocational or academic aspirations. Two critical questions arise from reported findings. First, what is the effectiveness of comprehensive FEP programs that incorporate an SEE component for the broader range of FEP patients, including those with no immediate specific interest in work or school? Second, to the extent that comprehensive FEP programs that include an SEE component do improve work or school outcomes, are these gains mediated by participation in SEE?

To address these questions, this study used data from a cluster randomized trial funded by the National Institute of Mental Health (NIMH): the Recovery After an Initial Schizophrenia Episode-Early Treatment Program (RAISE-ETP) study (Kane et al., 2016). RAISE-ETP compared outcomes of the comprehensive NAVIGATE care program for FEP to those of usual services (Community Care; CC). The RAISE-ETP study was an effectiveness trial conducted in routine service settings that did not require motivation for work or school as a prerequisite for admission. SEE was only one of several components of the NAVIGATE intervention. In addition, the usual community care condition also could include employment or rehabilitation services as they would be available in typical service systems in the US.

The current study contributes to previous FEP research by (1) examining whether participation in SEE mediates gains in instrumental functioning when offered in an effectiveness study as one component within a comprehensive specialty care program and is compared to usual care; (2) extending FEP outcome analyses to include employment earnings and receipt of public income supports (including payments from Social Security Disability and Supplemental Security Income programs); and (3) examining the broader relationship between receipt of public support income receipt and work-school participation.

2. Methods

The RAISE-ETP study design (Kane et al., 2015b), the clinical interventions (Mueser et al., 2015), and two-year clinical outcomes, including the CONSORT diagram of recruitment have been previously published (Kane et al., 2016). A total of 404 individuals aged 15–40 who presented for treatment for FEP and had taken antipsychotic medication for ≤6 months were enrolled between July 2010 and July 2012. Written informed consent was obtained from adult participants or from legal guardians for minors. The study was approved by the Institutional Review Board of the coordinating center and at each participating site. An NIMH Data and Safety Monitoring Board provided oversight. Thirty-four community mental health treatment centers were chosen following a national invitation and selection process and were randomized equally to provide either NAVIGATE or CC.

2.1. Intervention

2.1.1. Navigate

included four primary components: a) personalized medication management; b) family psychoeducation; c) individual, resilience-focused training (IRT) in illness self-management; and d) SEE. Weekly team meetings focusing on each service component facilitated communication and coordination between providers. NAVIGATE team members received ongoing training, on-site supervision, and external expert consultation for each intervention component. CC sites provided treatment following clinician choice and service availability. Treatment continued for up to 24 months.

2.1.2. SEE program

We assumed that many if not all FEP patients would be interested in the prospect of going to work or school (Iyer et al., 2011). Accordingly, SEE specialists met with all NAVIGATE patients to discuss how the SEE program could be helpful. For patients who were not initially interested in work or school, other interventions (especially IRT) sought to bolster motivation to work or attend school and encouraged participation in SEE, which was available at any time during the 24-month treatment period. SEE was based on principles of the IPS model (Becker and Drake, 2003; Drake et al., 2012), expanded to include school as in other FEP programs based on IPS (Killackey et al., 2008; Nuechterlein et al., 2008). Other than not requiring desire to work or attend school, SEE services were consistent with IPS; services were integrated with other clinical services of the NAVIGATE team; the focus was on competitive employment or enrollment in mainstream educational programs; emphasis was placed on rapid job search or enrollment in school commencing soon after enrollment in the program with no requirement for pre-vocational or pre-educational training; attention was given to patient preferences regarding job/school type and disclosure of psychiatric disorder; most services were provided in the community; follow-along supports were provided after job attainment or enrollment in school; and active benefits counseling was provided. Further details of the program are provided in Mueser et al. (2015).

The SEE intervention was standardized in a detailed manual (Lynde et al., 2014). Administratively, the director of the NAVIGATE team was designated as the supervisor of the SEE specialist, and weekly supervision sessions by the supervisor of the specialist were established as an expectation at the beginning of the project. Each NAVIGATE team received study funds to support at least at 5 h of SEE services per week. Using state and local resources, the availability of SEE specialists was expanded to 6–10 h per week at 9 NAVIGATE sites (52%), and to >10 h/week at 3 sites (17%).

SEE specialists participated in an initial 3-day training with their NAVIGATE team, and 7–8 other NAVIGATE teams, which was mostly devoted to breakout sessions focusing on the training of the specific interventions (e.g., SEE, IRT, etc.) supplemented by some team training. The directors of each NAVIGATE team participated in some of this SEE training. Following the initial training, twice-monthly group consultation calls were conducted with 5–7 SEE specialists per call. Program directors were also encouraged to join the calls. New specialists were trained through directed readings, individual training by the NAVIGATE director or one of the SEE specialists, shadowing other SEE specialists, participation on consultation calls, and enrollment in interactive online IPS courses. Among the 17 participating sites, 6 had IPS programs or previous IPS research projects at their agencies, and of these 4 had SEE specialists who were either part of IPS teams or had prior training in IPS.

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2.2. Measures

2.2.1. Participant characteristics and clinical status

Sociodemographic characteristics documented at baseline included age, gender, race, marital status, living situation, employment and school attendance in the previous 30 days, and the duration of untreated psychosis, measured as the difference between the date of first onset of symptoms and initiation of antipsychotic treatment. Clinical indicators included past psychiatric hospitalization, the Positive and Negative Syndrome Scale (PANSS; (Kay et al., 1987); the Clinical Global Impressions Severity Scale (Guy, 1976); the Calgary Depression Scale for Schizophrenia (CDSS; (Addington et al., 1993); the Quality of Life Scale (QLS; (Heinrichs et al., 1984); and participants' self-ratings of their overall mental or emotional health on a 0–100 (worst to best) scale. Clinical assessments of symptoms and quality of life were conducted by remote assessors using secure, two-way video-conferencing every six months for two years. Additional measures included a self-perceived stigma scale based on the average score on a six-item measure scaled from 1 to 7 (King et al., 2007) and participants' judgment of the likelihood that they would complete the two-year trial as a whole, and that they would complete the next scheduled assessment, both rated on 0–9 Likert scales ("not at all" to "markedly"; (Leon et al., 2007).

2.2.2. SEE program fidelity

Adherence to the SEE manual was reviewed over the course of the study by the SEE consultants based on a combination of group consultation calls and review of patient rosters at each site. Fidelity to the SEE program over the entire course of the study was rated at the end by two raters based on these logs and administrative records pertaining to the following nine domains: attempted engagement in SEE of all patients in NAVIGATE program, frequency of contacts, focus of employment specialists exclusively on work or school, integration of SEE services with the overall NAVIGATE team, rapid search for competitive work or integrated school, provision of services in the community, follow-along supports provided after job obtainment or school enrollment, weekly supervision by NAVIGATE director, and attendance by SEE specialist and NAVIGATE director on expert consultation calls. Ratings were provided for each of the 9 domains on behaviorally anchored 4-point scales corresponding to 1 = poor, 2 = limited, 3 = basic, and 4 = good (potential range for total scores = 9–36). A score of "3" ("basic") was considered the minimum for acceptable implementation. Total scores for the 17 sites ranged from 21 to 35. Using the average score across all 9 items to indicate the overall fidelity of a site, 4 sites were in upper range of basic to good (≥3.5), 11 sites were in the lower basic to good range (≥3.0 and <3.5), 1 site was in the upper range of limited to basic (≥2.5 and <3.0), and 1 site was in the lower limited to basic range (≥2.0 and <2.5). The highest rated items on the scale were attendance of the SEE specialist at the NAVIGATE team meetings and attempted engagement of all patients in SEE, for which all programs were rated "basic" (3) or "good" (4). The lowest rated item was provision of SEE services in the community (an especially resource intensive activity because it requires extensive travel time), for which only 8 programs were rated at the basic or good level. The frequency of contacts item indicated that employment specialists had at least twice a month contacts (rating = 4) with clients at 13 sites, monthly contacts (rating = 3) at 2 sites, once every other month (rating = 2) at 1 site, and less than once every other month at 1 site (rating = 1). Caseload size based on the maximum number of patients receiving SEE services from a specialist at one time ranged from 4 to 20, with a mean of 10.72 patients per SEE specialist.

2.2.3. Service utilization and sources of income

Research assistants interviewed participants monthly to complete the Service Use and Resource Form (SURF) (Rosenheck et al., 2016; Rosenheck et al., 2006). The SURF documents client-reported days of employment and school attendance, as well as use of inpatient, emergency, and outpatient mental health and medical services over the previous month. The SURF also includes specific questions concerning the number of days on which participants receive services comparable to the four specific NAVIGATE interventions, including information on treatment activities related to getting a job or attending school. Every three months additional questions addressed sources of income, including employment earnings and public support payments including food stamps, unemployment insurance, housing subsides, and disability payments (i.e., Social Security Disability [SSD] and Supplemental Security Income [SSI]).

2.3. Outcomes

Days of paid employment and school attendance were the principal outcomes. They were combined for analytic purposes into a dichotomous measure of any participation in work or school over the previous month and, secondarily, as a continuous measure of the number of days of participation in work or school over the previous month. Separate measures of participation in work and in school were also examined. SSD and SSI measures were summed to represent Social Security Administration (SSA) income. These were analyzed as both dichotomous variables (receipt of any employment, public support, or SSA income) and as continuous measures (dollars received per month from each source – including 0 s for those who received no payments).

2.4. Statistical methods

Analysis proceeded in several steps. First, randomized groups were compared on mixed model analysis of baseline characteristics adjusting for the nesting of individuals within sites.

In the principal analysis, generalized estimation equation (GEE) models were used to determine whether there were significant group by time interactions between treatment groups on dichotomous and continuous work or school outcomes. That is, were there significant differences between treatment groups in the *rate of improvement* in participation in work or school over the two years of the trial? These analyses were adjusted for the clustering of individuals within sites and for observations at different time points among individuals.

Because of baseline differences in the primary outcome, a main effect was included for treatment in addition to the main effect of time and the interaction of treatment by time. As in previous RAISE-ETP analyses (Kane et al., 2016) a square-root transformation of time produced the best model fit, reflecting greater differences in improvement early as compared to later in the two-year follow-up period. Negative binomial GEE models were used for the analyses of days of work-school participation per month, as well as of receipt of employment earnings and both overall public support and SSA payments. Negative binomial models were used because the variances of these variables are greater than the means.

The analysis of the mediating effect of SEE on work-school outcomes was evaluated where significant treatment group by time interactions were observed. Since all NAVIGATE participants were expected to meet with the SEE specialist at least once, and a second exploratory meeting was expected for many patients, we chose three or more contacts with the SEE specialist over the course of the study to define minimal engagement in the NAVIGATE SEE program. For comparison, SEE engagement among CC participants was defined as three or more treatment contacts involving assistance with work or school goals.

For analyses of mediating effects of SEE, a 3-way interaction term representing treatment group by time by receipt of three or more SEE contacts (SEE ≥ 3) was added to the terms representing treatment group, square root of time and the interaction of treatment by the square root of time. If the term representing treatment by time was no longer significant in this model, this was considered evidence that participation in SEE (i.e., receipt ≥3 SEE contacts) mediated the treatment

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group effects on work-school involvement. If the interaction of treatment group by time by SEE ≥ 3 was significant, this was considered even stronger evidence of the independent effect of SEE.

Because of extensive missing data (51% on the sample completed the two-year assessment) and differential attrition between groups, marginal structural modeling was used to adjust for the specific characteristics associated with observations that were missing (Robins and Finkelstein, 2000). In this approach, a model is constructed that predicts the probability that each possible observation for each client will be successfully obtained. This model is based on individual client baseline characteristics; whether or not the previous observation was successfully obtained; previous follow-up scores on symptoms and quality of life (based on the most recent observation obtained of these outcomes); and a measure obtained from the client at each follow-up observation of their expectation of: a) whether they will complete the two-year study, and b) whether they will attend the next interview. Based on this model the predicted probability was calculated that each observation would actually be completed. This predicted probability can be thought of as a propensity score representing the likelihood that a follow-up observation would be obtained. Follow-up observations were then weighted inversely by this probability. Thus observations of the type that were *less* likely to be completed were given *more* weight in the analysis, and observations of the type that were *more* likely to be completed were given relatively *less* weight. As a result of this weighting the analyses are expected to be more representative of results that would have been obtained had all follow-up assessments been completed.

Analyses were performed using SAS version 9.4 (SAS Institute, Inc.).

3. Results

At baseline NAVIGATE participants had worse average PANSS total scores ($p < 0.02$) as compared to CC; were significantly more likely to be male (77.6% vs. 66.2%; $p = 0.05$); less likely to have had a prior hospitalization (76.3% vs. 81.6%; $p < 0.05$), and less likely to report current participation in work or school (25% vs. 37%; $p < 0.03$). The last difference is of special relevance to this analysis since it is the primary outcome variable in this study.

Altogether 150/220 (68.2%) NAVIGATE participants received 3 or more SEE contacts during the trial while only 43/181 (23.7%) of CC participants received assistance with work or school on 3 or more occasions. As depicted in Fig. 1, NAV-CC group differences were quite pronounced by six months although over half (51%) of NAV participants who received 3 or more SEE contacts did so 6 months or more after program entry.

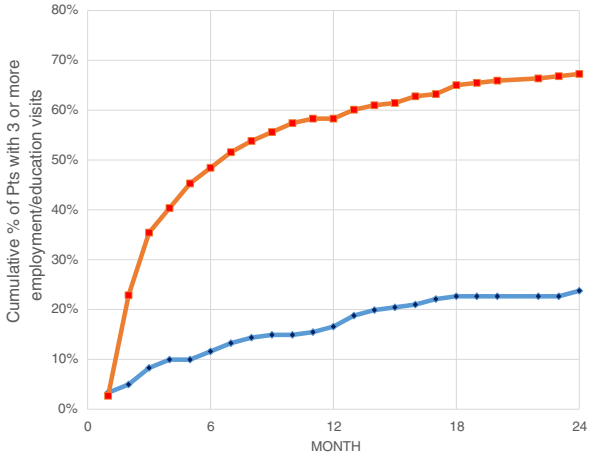

Fig. 1. Cumulative proportion of patients with 3 or more supported employment/education visits.

Participants with SEE ≥ 3 were compared to those with SEE < 3 within each randomized group. There were no significant baseline differences between CC participants who subsequently received ≥3 vocational rehabilitation services and those who did not. However, among NAVIGATE participants, those with ≥3 SEE visits had significantly lower CDSS depression scores at baseline compared to those with fewer SEE visits (mean = 4.0, sd = 3.9 vs 5.97, sd = 5.02; F = 10.7, $p = 0.0012$).

Unadjusted longitudinal data reflecting the proportion of patients in each group who were either working or going to school clearly shows the baseline difference reported above. Increases in this outcome were greater among NAVIGATE than CC patients so that by six months the proportions were roughly equivalent (Fig. 2), a time frame that corresponds to the point at which group differences in the proportion who had received 3 or more SEE visits become quite pronounced.

To address biases due to differential patterns of missing data between groups a model that predicted the probability of completing follow-up assessments was constructed. The model had a high c-statistic of 0.86 indicating that it strongly predicted whether a participant would complete the next planned assessment. The strongest predictor of assessment completion was completion of the immediate previous assessment ($p < 0.0001$), followed by assessment at earlier time points in the trial ($p < 0.0001$), randomization to NAVIGATE (i.e., differential attrition) ($p < 0.0001$), being older ($p < 0.0001$), having higher recent QLS scores (better functioning) and lower CDSS scores (both with $p < 0.0001$), higher subjective quality of life ratings ($p = 0.0006$), male ($p < 0.003$), expecting to complete the trial ($p = 0.001$), and having slightly higher stigma scores ($p = 0.01$). Overall, engagement in rehabilitative services that were focused on work or school participation was associated with lower likelihood of successful follow-up ($p < 0.003$). However, treatment group interaction analyses showed NAVIGATE participants in particular were *more* likely than CC patients to complete the next assessment if they were engaged in SEE ($p < 0.0001$), had lower stigma sores ($p < 0.002$), and had not been hospitalized at the time of the previous interview ($p < 0.0005$).

The work-school outcome model, inversely weighted for the probability of successful follow-up according to the above model, showed a significant group by time interaction (estimate = 0.012, $p = 0.0486$), indicating a greater increase in the likelihood of work-school participation over time for NAVIGATE, as well as a main effect of NAVIGATE reflecting the previously identified baseline difference in work-school participation (estimate = −0.60, $p < 0.005$) (Fig. 3). For NAVIGATE, work-school-participation increased 58.2% from baseline to 24 months (from 27.8% to 43.2%), compared to only 6.1% for CC participants (40.7% to 43.2%); with work-school participation for both NAVIGATE and CC of 43.2% at 24 months (Table 1).

The addition of a three-way interaction term representing group by time by ≥3 SEE visits eliminated the significance of the group by time interaction (estimate =.

−0.0019, $p = 0.98$), but showed a significant main effect for the interaction term including ≥3 SEE visits (estimate = 0.16, $p < 0.05$). This suggests that improved work-school outcomes for NAVIGATE were mediated by participation in SEE (see modeled data in Fig. 4).

Since DUP was a significant moderator of quality of life outcomes, the primary outcome of RAISE-ETP (Kane et al., 2016), we evaluated the moderating effects of DUP in the analysis group by time outcomes of employment or school attendance and found no significant moderating effect (Z = −0.1.37, $p = 0.17$), arguing against a moderating effect for DUP on this outcome.

Table 1 compares NAVIGATE and CC groups on work and school outcomes, disability status, and income. The analysis of the number of days per month in work or school showed a trend for NAVIGATE (estimate = 0.12, $p = 0.07$). Otherwise, there were no significant differences between NAVIGATE and CC. on (1) work considered alone (estimate = 0.097, $p = 0.16$); (2) school participation considered alone (estimate =

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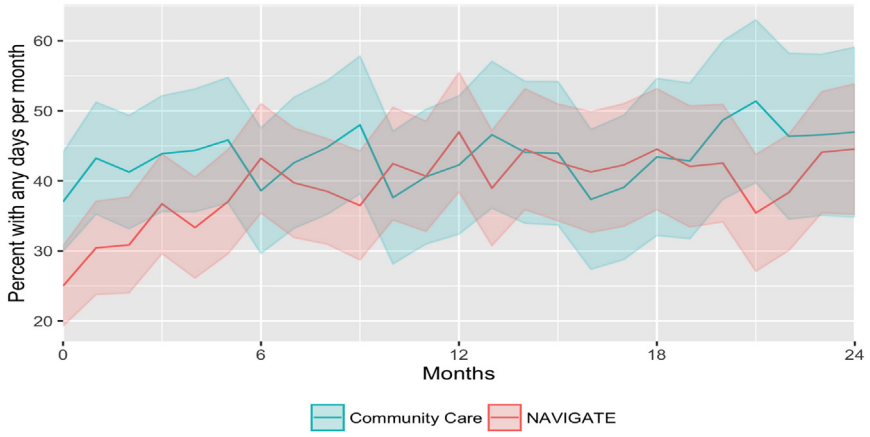

Fig. 2. Percent with any work or school days per month (raw unadjusted data with 95% confidence intervals [shading]).

0.10, $p = 0.18$); (3) monthly earned income (estimate = 5.51, $p = 0.71$); (4) the proportion of patients receiving any public support income (estimate = 23.55, $p = 0.10$); (5) the proportion receiving any Social Security income (estimate = 0.0086, $p = 0.89$); or (6) monthly income from Social Security benefits (estimate = 4.25, p = 0.71).

Finally, we explored the relationship of treatment and work or school participation in a series of models which also included a covariate representing time-varying levels of overall public support income, and, in a separate analysis, a covariate representing time-varying levels of SSA income. These models showed highly significant negative associations of both total public support income (estimate = −0.0016, $p < 0.0001$) and Social Security income (estimate = −0.0018, $p < 0.0001$) with participation in work or school. In addition, there were no longer significant treatment group by time interaction effects with these terms in the models ($p = 0.35$ and $p = 0.22$, respectively).

4. Discussion

This secondary analysis of data from the RAISE-ETP cluster randomized trial found that persons recovering from FEP who received comprehensive, coordinated care received far more SEE services and showed significantly greater increases in work or school participation over two-years compared to those who received usual community care. It is difficult to compare our results for the improvement in work or school participation for NAVIGATE (58.2%) to treatment results obtained in other randomized controlled trials that tested IPS-SEE interventions for FEP (Bond et al., 2015) as there are few comparable effectiveness studies carried out in such real-world contexts.

The importance of the SEE component for improving work and school outcomes in NAVIGATE is supported by our finding that engagement in SEE services, defined as having ≥3 SEE contacts during the two-year trial, appears to mediate work and school recovery. These effects are especially notable in view of the fact that, while most research studies of SEE have included full-time employment specialists (e.g., (Killackey et al., 2008; Nuechterlein et al., 2008), SEE specialists at NAVIGATE sites provided services at a much lower level than that of a full time position. Although it is clear that far more patients received SEE at NAVIGATE sites than received parallel vocational services at CC sites, limitations in the availability of SEE staff resources may have reduced both direct patient contact with the SEE specialist, and perhaps more importantly the time available to provide community (rather than clinic) based services, as suggested by the low fidelity ratings on this domain. This may have limited the ability of the SEE specialists to provide community-based supports following job or school placement, as well as the in-person development of jobs or relationships with local educational institutions, activities that are central to the effectiveness of IPS (Becker and Drake, 2003) and which typically involves no direct patient contact.

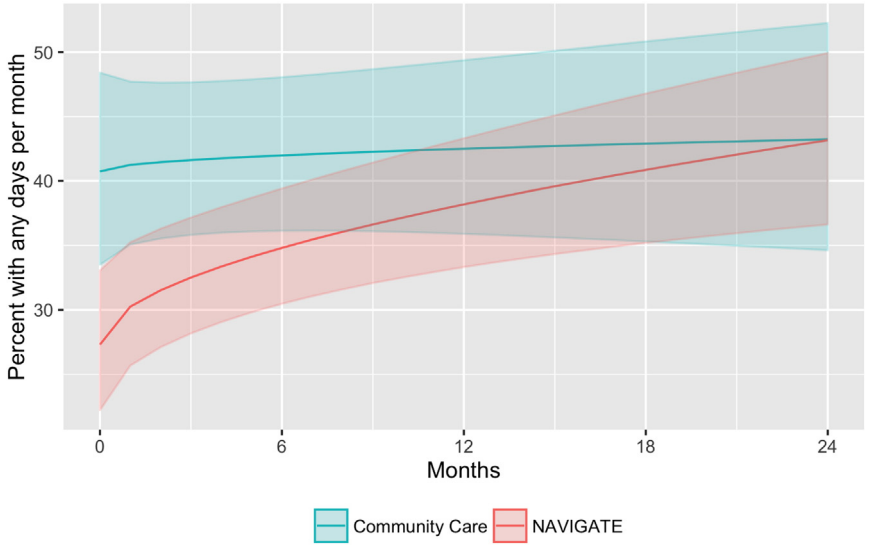

Fig. 3. Percent with any work or school days per month (unadjusted percentages with 95% confidence intervals [shading]) (treatment by time: $p = 0.048$).

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Table 1
Fitted means: Work or school participation, public support, social security disability (SSDI or SSI).

		Baseline		Month 6		Month 12		Month 18		Month 24	
Number of community care (CC) participants		$N = 181$		$N = 133$		$N = 116$		$N = 96$		N = 83	
Number of NAVIGATE (NAV) participants		$N = 223$		$N = 182$		$N = 166$		N = 156		N = 144	
Percent (standard error, s.e.)		%	s.e	%	s.e	%	s.e	%	s.e	%	s.e
Any participation in work or school (%)	CC	40.7	3.8	41.9	3.0	42.5	3.4	42.9	4.0	43.2	4.5
	NAV	27.3	2.8	34.8	2.3	38.2	2.5	40.9	3.0	43.2	3.4
Any participation in work (%)	CC	20.2	3.1	24.8	2.6	27.0	2.9	28.7	3.4	30.2	4.0
	NAV	13.6	2.0	20.8	1.9	24.4	2.2	27.5	2.6	30.3	3.1
Any participation in school (%)	CC	25.3	3.6	22.7	2.7	21.7	3.0	20.9	2.8	20.3	2.8
	NAV	16.6	2.7	18.2	2.0	18.9	2.2	19.4	2.5	19.9	2.8
Receipt of any public support including disability) (%)	CC	40.7	4.0	49.3	3.5	53.0	4.2	55.7	4.8	58.0	5.4
	NAV	37.2	3.5	50.3	3.0	55.8	3.3	59.9	3.6	63.3	3.9
Receipt of Any SSDI or SSI Disability income (%)	CC	14.3	2.9	28.1	3.4	35.8	4.2	42.3	5.0	47.9	5.8
	NAV	5.8	1.5	21.5	2.6	33.8	3.2	45.1	3.7	55.1	4.2
Mean (standard error, s.e.)		Mean	S.E.	Mean	S.E.	Mean	S.E.	Mean	S.E.	Mean	S.E.
Number of days of participation in work or school (mean)	CC	6.57	0.76	7.00	0.61	7.19	0.69	7.33	0.80	7.46	0.93
	NAV	4.10	0.49	5.56	0.46	6.31	0.52	6.96	0.62	7.55	0.75
Number of days of participation in work (mean)	CC	2.55	0.45	3.40	0.42	3.84	0.48	4.21	0.59	4.54	0.72
	NAV	1.54	0.28	2.72	0.31	3.44	0.37	4.12	0.46	4.80	0.58
Number of days of participation in school (mean)	CC	4.14	0.63	3.53	0.48	3.31	0.52	3.15	0.57	3.02	0.61
	NAV	2.69	0.45	2.78	0.34	2.82	0.36	2.85	0.41	2.87	0.46
Employment earnings (entire sample, including 0 s)($)	CC	96.5	28.3	173.3	29.1	205.1	38.1	229.5	46.3	250.1	53.7
	NAV	61.2	17.5	151.4	19.9	188.8	25.0	217.5	29.6	241.7	33.8
Amount of public support income Including Disability(entire sample, including 0 s) ($)	CC	248.3	42.1	344.4	37.2	384.2	41.4	414.8	46.5	440.5	51.7
	NAV	162.6	24.7	316.4	23.8	380.1	28.2	429.0	32.6	470.2	36.8
Amount of disability income (entire sample, including 0 s) ($)	CC	108.5	29.3	213.6	27.6	257.2	32.0	290.6	36.7	318.8	41.2
	NAV	13.2	16.8	190.0	18.7	263.3	24.3	319.5	29.3	366.9	33.9

Previous controlled research on IPS-based SEE programs for the FEP population has focused on participants with a stated interest in work or school. It is unknown how many persons with FEP were excluded from these studies because of a lack of interest in work or school. However, it is notable that over half of RAISE-ETP patients who had 3 or more SEE contacts began these contacts *6 months or more* after program entry, suggesting that many eventual participants in SEE were not initially interested in employment or school. These data raise questions about the generalizability of findings from earlier studies of IPS-SEE (Killackey et al., 2008; Nuechterlein et al., 2008) to the broader population of people who experience FEP. The present study, in contrast, included all persons with FEP who sought treatment (without regard to having an initial employment or educational goal), many of who appeared to lack initial motivation to work or attend school, but who developed such motivation over 6 months or longer. This finding supports the inclusion of SEE as a core component of comprehensive treatment for the broader population of persons with FEP, including in the NAVIGATE program, and suggests that permitting flexible access to SEE services over the long-term may be critical to engaging the greatest number of patients in pursuing employment or educational goals.

Desire for work is a potent predictor of subsequent work in young persons with schizophrenia-spectrum disorders (Mueser et al., 2001). In the present study, approximately one-third of participants in the NAVIGATE program never engaged in SEE (i.e., they had two or fewer contacts with the SEE specialist over two years). To the extent that failure to engage in SEE is a proxy for less interest in work or school, the overall rates of work or school involvement reported here are likely to be lower than would be the case for the subgroup of FEP participants who had immediate work or educational goals.

Both NAVIGATE and CC participants showed a steady increase in the proportion receiving any public support or specific Social Security payments over time. This increase is likely to reflect the pursuit of disability

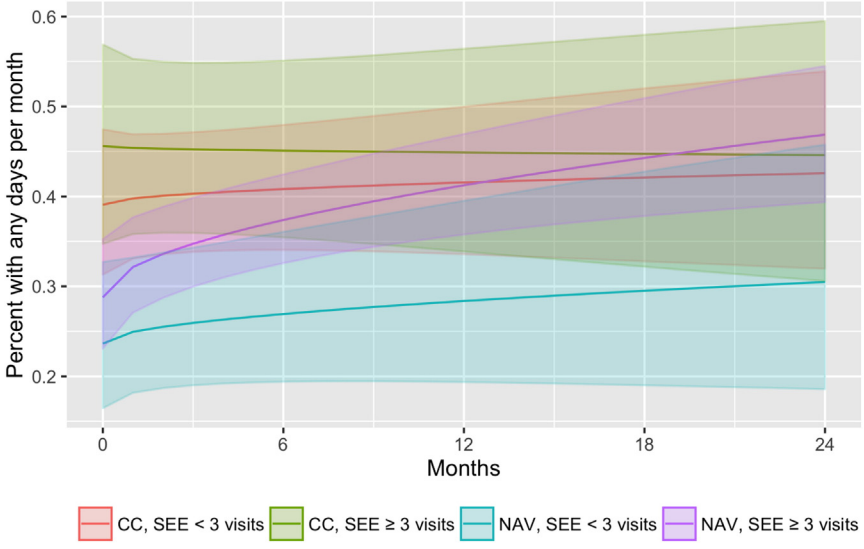

Fig. 4. Percent with any work or school days per month by level of Supported Employment/Education (fitted model with 95% confidence intervals ([shading]) (≥3 SEE visits) (fitted model: Trt*time: $p = 0.98$; Trt*time*SEE ≥ 3:$p = 0.045$).

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related income support but perhaps even more importantly, Medicaid eligibility for health insurance. Many study participants also received other services from agencies that depend on Medicaid income for financial viability. Discussions with site leaders at NAVIGATE sites and one qualitative study (Goldman et al., 2012; Goldman et al., 2013) suggested that some RAISE-ETP programs, like many community mental health programs in the United States, encourage prompt application for Social Security benefits to assure support for anticipated treatment needs. Receipt of these benefits was strongly negatively associated with employment, and was possibly an unintended consequence of assuring access to needed healthcare or income supports. This negative relationship between receipt of public support income and work-school participation could reflect one of three processes: (1) an income effect (receipt of public support income reduces the economic incentive or need for employment), (2) a disability impairment effect (patients who receive disability are less capable of working because of more severe impairment), or (3) apprehension about working for fear of losing needed benefits. All three processes are likely involved. The negative relationship between public support income and employment has been reported in many prior studies (Drew et al., 2001; Rosenheck et al., 1995; Rosenheck et al., 2000; Rosenheck et al., 2006), including among persons receiving supported employment (McGurk and Mueser, 2006), but not in all studies (Mares and Rosenheck, 2007).

Several methodological limitations require comment. As noted above, there was a significant difference between treatment groups in work-school participation at baseline. Such imbalances are not uncommon in cluster-randomized trials because of the relatively small number of entities being randomly assigned (34 sites in RAISE-ETP). To address this imbalance we included a term representing treatment group assignment in our models but it must be acknowledged that our primary finding, that there was a difference in the amount of improvement from baseline levels could have been influenced by the difference between groups in baseline starting points.

Second, there was considerable attrition of almost 50% over the two years of the study. This is an expectable problem in any study of people with schizophrenia, and even more likely in studies of FEP or in long-term, multi-site, real-world effectiveness studies of both psychosocial interventions (Cook et al., 2005; Petersen et al., 2005) and pharmacologic interventions (Lieberman et al., 2005; McEvoy et al., 2014). We used what have been called "marginal structural models" to address potential biases introduced by differences between treatment groups in rates and correlates of attrition. Although this method statistically compensates for potential biases introduced by differential attrition it may not fully address this limitation.

Third, although we examined the role of SEE as a mediator of group differences, it remains possible that patients who were more involved in SEE were different than those who were not in unmeasured ways, such as motivation for going to work or school. Baseline analysis showed NAVIGATE patients who had fewer than 3 visits had more severe depressive symptoms than those who had three or more visits and there may have been other differences in motivation for work or other characteristics. In addition, other components of NAVIGATE, not available at CC sites, may also have played a role in fostering the increased rates of work-school participation in the experimental treatment group. Thus, in this descriptive secondary analysis we are unable to conclusively isolate the mediating effect of having 3 or more SEE contacts on employment outcomes and acknowledge that the mediating effects of SEE may be partial since other patient characteristics and NAVIGATE services may have also played an influential role.

Finally, we note that group differences in employment outcomes in this study were more modest than in most IPS or IPS-SEE studies. Several differences between SEE component of the NAVIGATE program reported here and previously published studies of the IPS or IPS-SEE models may have contributed to these weaker findings. IPS and IPS-SEE are usually implemented by a vocational team that includes at least two full time employment specialists and a supervisor, with site-based training that includes community trips with specialists, and follow-up consultation (Becker and Drake, 2003). The "shadowing" (i.e., following along during community visits with patients) of trained employment specialists at another site is another common feature of training in IPS and IPS-SEE. In contrast, this real-world effectiveness study relied mainly on remote training and consultation of the SEE specialists, with no site-based training provided or opportunities to shadow experienced employment specialists from other programs. The use of live, experiential training methods similar to those employed in IPS or IPS-SEE could have resulted in more skilled SEE specialists, and contributed to stronger work and school outcomes.

Also in contrast to the full time employment of employment specialists in IPS or IPS-SEE, most of the SEE specialists worked significantly less than half-time on their NAVIGATE team, limiting their ability to conduct in-person job development and establish relationships with educational institutions within their local community, activities which are frequently conducted without the patient and are thought to be crucial to successful outcomes (Becker et al., 2016; Leff et al., 2005). Thus, higher levels of staffing for the SEE program would have permitted more in-person work and school development, and potentially increased its effectiveness at enhancing employment and educational outcomes.

In spite of these limitations, the RAISE-ETP is the largest, longest, most rigorous study of specialized coordinated care for FEP yet conducted in the US and the first US effectiveness study of such an intervention carried out in real-world settings. The findings suggest that the comprehensive, team-based treatment approach implemented in the NAVIGATE intervention resulted in far greater engagement in work-school oriented rehabilitation services, and ultimately in a greater improvement in work and school outcomes and that this difference in outcomes appears to be mediated, at least in part, by greater engagement in the SEE component of the intervention.

Contributors

Robert Rosenheck and Kim T. Mueser wrote the first draft of the paper. Kyaw Sint, Haiqun Lin were responsible for conducting analyses and statistics. David W. Lynde, and Shirley M. Glynn provide training to employment specialists. Somaia Mohamed contributed to the literature review and preparation of the manuscript. John M. Kane, Delbert G. Robinson, Nina R. Schooler led the design of the study. Patricia Marcy contributed to the design and implementation of the study. *All authors contributed to and have approved the final manuscript.*

Potential conflicts of interest

J.M.K. has been a consultant for Alkermes, Amgen, Bristol-Myers Squibb, Eli Lilly, EnVivo Pharmaceuticals (Forum), orest, Genentech, H. Lundbeck, Intra-Cellular Therapies, Janssen Pharmaceutica, Johnson and Johnson, Merck, Novartis, Otsuka, Pierre Fabre, Reviva, Roche, Sunovion, and Teva; he has received honoraria for lectures from Bristol-Myers Squibb, Genentech, Janssen, Lundbeck, and Otsuka; and he is a shareholder in MedAvante and n Vanguard Research Group. D.G.R. has been a consultant to Asubio, Otsuka, and Shire; and he has received grants from Bristol-Myers Squibb, Janssen, and Otsuka. N.R.S. has served on advisory boards or as a consultant for Abbott, Alkermes, Amgen, Eli Lilly, Forum (formerly EnVivo), Janssen Psychiatry, Roche, and Sunovion; she has received grant or research support from Genentech, eurocrine, and Otsuka; and she has served on a data monitoring board for Shire and on the faculty of the Lundbeck International Neuroscience Foundation. The authors and their associates provide training and consultation about implementing NAVIGATE treatment that can include compensation. These activities started only after data collection or the manuscript was completed. At the time of publication, D.G.R. had received compensation for these activities. R. R, K.T.M., K.S., H.L., D.W. L, S.M.G., P. M and S.M. report no financial relationships with commercial interests.

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Executive Committee: John M. Kane, M.D., Delbert G. Robinson, M.D., Nina R. Schooler, Ph.D., Kim T. Mueser, Ph.D., David L. Penn, Ph.D., Robert A. Rosenheck, M.D., Jean Addington, Ph.D., Mary F. Brunette, M.D., Christoph U. Correll, M,D., Sue E. Estroff, Ph,D., Patricia Marcy, B.S.N., James Robinson, M.Ed.

NIMH Collaborators: Robert K. Heinssen, Ph.D., ABPP, Joanne B. Severe, M.S., Susan T. Azrin, Ph.D., Amy B. Goldstein, Ph.D.

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