

A Randomized Controlled Trial of the Effects of Early Intervention Services On Insight in First Episode Psychosis

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Background and Hypothesis Impaired insight into one's illness is common in first episode psychosis (FEP), is associated with worse symptoms and functioning, and predicts a worse course of illness. Despite its importance, little research has examined the effects of early intervention services (EIS) on insight. **Designs:** This paper evaluated the impact of EIS (NAVIGATE) on insight compared to usual community care (CC) in a large cluster randomized controlled trial. Assessments were conducted at baseline and every 6 months for 2 years. **Results:** A multilevel regression model including all time points showed a significant time by treatment group interaction ($P < .001$), reflecting greater improvement in insight for NAVIGATE than CC participants. Impaired insight was related to less severe depression but worse other symptoms and functioning at baseline for the total sample. At 6 months, the same pattern was found within each group except insight was no longer associated with depression among NAVIGATE participants. Impaired insight was more strongly associated with worse interpersonal relationships at 6 months in NAVIGATE than in CC, and changes in insight from baseline to 6 months were more strongly correlated with changes in relationships in NAVIGATE than CC. **Conclusions:** The NAVIGATE program improved insight significantly more than CC. Although greater awareness of illness has frequently been found to be associated with higher depression in schizophrenia, these findings suggest EIS programs can improve insight without worsening depression in FEP. The increased association between insight and social relationships in NAVIGATE suggests these 2 outcomes may synergistically interact to improve each other in treatment.

Key words: recent onset psychosis/social functioning/RAISE-ETP/schizophrenia

Introduction

Impaired insight into one's illness is a cardinal feature of schizophrenia, present in the vast majority of persons who are symptomatic. Reduced insight is associated with worse psychosocial functioning,^{1,2} more severe psychotic, negative, and disorganized symptoms,³⁻⁶ and a more guarded prognosis.^{7,8} However, reduced insight in schizophrenia is also associated with less severe depression,⁹⁻¹¹ and better subjective mental health functioning.¹²⁻¹⁴ This divergence in associations between better insight, better psychosocial functioning, and less severe overall symptoms with the exception of worse depression and subjective well-being has been referred to as the "paradox" of insight.¹⁵⁻¹⁷

The importance of impaired insight has also been demonstrated in people who have recently experienced the first episode of psychosis (FEP). Specifically, impaired insight in persons with an FEP has been shown to be related to less severe depression but worse other symptoms and psychosocial functioning,¹⁸⁻²⁰ and to predict a worse course of illness.^{21,22} However, despite the importance of impaired insight in the early course of schizophrenia, little research has examined the effects of early intervention specialty (EIS) programs on insight. For example, a recent meta-analysis of 18 randomized controlled trials of EIS programs found that none of the studies reported the effects of an EIS program on insight.²³

The present paper was aimed at evaluating the impact of a well-characterized EIS service, the NAVIGATE program,²⁴ on insight compared to usual community care (CC) in the context of a large cluster randomized controlled trial, the Recovery After Initial Schizophrenia Episode-Early Treatment Program (RAISE-ETP).^{25,26} In addition, because the NAVIGATE program provides

a combination of psychoeducation about psychosis and its treatment (both to individuals and family members), destigmatizing and recovery-oriented messages designed to instill hope, positive psychology to enhance resilience, teaching strategies for coping with symptoms, skills training to improve social relationships, and supports for involvement in work or school, all in the context of helping the person work toward personal goals,²⁴ we explored whether associations between impaired insight and symptoms and psychosocial functioning at baseline changed during treatment for participants in NAVIGATE compared to the usual treatment group.

Methods

The RAISE-ETP study was a cluster randomized control trial with 34 participating sites across 21 states within the United States randomized to provide 1 of 2 types of treatment for a 2-year period: usual CC or an early intervention service, the NAVIGATE program.^{24,26} CC consisted of the usual treatment offered for FEP patients at the individual site.

The NAVIGATE program includes 4 treatment components (individual resiliency training (IRT), family psychoeducation, collaborative medication management, and supported education and employment), which are implemented by a team that meets weekly to coordinate services and review progress.²⁴ IRT, the individual therapy component, is organized into a series of 14 topic areas (or modules). The first seven of these modules are recommended for all FEP participants (and include orientation, goal setting and treatment planning, psychoeducation, relapse prevention planning, processing the initial psychotic episode, developing resiliency, and building a bridge to one's goals), while the remaining seven modules are selected by the clinician and client depending on the person's needs (and include dealing with negative feelings, coping with symptoms, developing good relationships, substance use, nutrition and exercise, smoking, and further development of resiliency).²⁷ For further details see Mueser et al. (2015) and the NAVIGATE training website (<https://navigateconsultants.org>).

Participants

A total of 404 individuals met inclusion/exclusion criteria and participated in the study. Participant characteristics by treatment group are presented in Table 1. Inclusion criteria for the study were: (1) between the ages of 15 and 40 years, (2) experiencing a FEP, (3) less than 6 months prior cumulative use of antipsychotic medication, and (4) diagnosis of schizophreniform disorder, schizophrenia, schizoaffective disorder, brief psychotic episode, or psychosis not otherwise specified. Exclusion criteria were: (1) diagnoses of substance-induced

Table 1. Participant Characteristics

	Community Care		NAVIGATE	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Age	23.08	4.902	23.18	5.205
Duration of untreated psychosis	211.43	277.486	178.91	248.731
	<i>N</i>	%	<i>N</i>	%
Gender				
Male	120	66.3	173	77.6
Female	61	33.7	50	22.4
Ethnicity				
Hispanic	18	9.9	55	24.7
Not Hispanic	163	90.1	168	75.3
Race				
American Indian/Alaska Native	6	3.3	15	6.7
Asian	6	3.3	6	2.7
Black or African American	89	49.2	63	28.3
Native Hawaiian/Pacific Islander	0	0	1	0.4
White	80	44.2	138	61.9
Marital status				
Married	10	5.5	14	6.3
Divorced/separated	8	4.4	14	6.3
Never married	163	90.1	195	87.4
Current student				
No	134	74	188	84.3
Yes	47	26	35	15.7
Currently Employed				
No	151	83.4	195	87.4
Yes	30	16.6	28	12.6

psychosis, psychosis due to general medication condition, or affective psychosis, (2) clinically significant head trauma or other serious medical conditions, or (3) non-English speaking. Written informed consent was obtained from all participants, and those who are under 18 provided assent with their parent/guardian providing written consent on their behalf. Institutional review board approval was obtained for all sites and all study practices were overseen by the NIMH Data and Safety Monitoring Board.

Measures

Outcome assessments of clinical and psychosocial functioning, and subjective evaluation were conducted via videoconferencing at baseline and 6, 12, 18, and 24 months later by centrally trained interviewers who were blind to participants' treatment assignment. The Structured Clinical Interview for Axis I DSM-IV disorders (SCID)²⁸ was used to assess primary psychotic diagnosis, lifetime substance use disorder, and duration of untreated psychosis (DUP) at baseline. Due to the wide range in DUP, a median split (74 weeks) was used to dichotomize participants into low vs high DUP.^{26,29}

Clinical Measures

The Calgary Depression Scale for Schizophrenia (CDSS) was used to assess depression.³⁰ The CDSS is a 12-item measure using a Likert scale to measure multiple symptoms of depression over the past week, including interviewer observation.

The Positive and Negative Syndrome Scale (PANSS)³¹ was used to measure symptoms over the past week, with the Wallwork 5-factor model³² (including positive, negative, depression, excitement, and disorganization factors) employed for statistical analyses. PANSS ratings are made on a seven-point Likert scale with higher ratings representing more severe symptoms. Insight was measured with the Lack of Judgement and Insight item on the PANSS, which evaluates the person's unawareness of having a psychiatric condition and the need for treatment. The lowest rating on this item, absent (1), corresponds to individuals who recognize they have a psychiatric disorder that requires treatment (recognition of a specific disorder or diagnosis is not required), and which is reflected by realistic short- and long-term planning. Mild impairment, (2) reflects clear recognition of having a psychiatric disorder but underestimation of its seriousness and implications for treatment and poorly conceived planning, while moderate impairment, (3) reflects only shallow awareness of having a disorder and recognition of symptoms, with need for treatment limited to reduction of distress. Severe levels of impairment (ratings 4–7) correspond to individuals who deny the presence of a current psychiatric disorder and need for treatment, with moderately severe, (4) for those who acknowledge a disorder in the past, severe, (5) for those who deny ever having a disorder but who are compliant with treatment, and extremely severe, and (6) for similar individuals but who are not compliant with treatment. This PANSS item is strongly correlated with other measures of insight,³³ including the Birchwood Insight Scale (BIS)³⁴ and the Scale of Unawareness of Mental Disorder (SUMD),³⁵ and has been widely used in research on insight in schizophrenia.^{36–43}

Self-Report Subjective Measures

An abbreviated version of the Stigma Scale⁴⁴ was used to measure perceptions of mental health stigma. Seven items from the Stigma Scale were used in the RAISE-ETP study to assess experiences of discrimination and their interpretation of how others view them in the context of their mental illness. Six of the items were moderately intercorrelated with each other but not the seventh item, which was dropped in a previous analysis.⁴⁵ The 6-item measure showed moderate internal consistency ($\alpha = 0.72$). Mental health well-being was assessed using 18 items from the longer version of the Psychological Well-being Scale⁴⁶ showing fair internal

consistency ($\alpha = 0.51$). This scale captured ratings of different aspects of well-being such as quality of life, focus on goals, happiness with relationships, and feelings of independence.

The Brief Evaluation of Medication Influences and Beliefs Scale⁴⁷ is a 4-item scale that assesses attitudes toward antipsychotic medication. Ratings are made on a 7-point Likert scale and measures agreement with the following statements: (1) medication prevents a relapse, (2) side effects from antipsychotics bother me (reverse scored), (3) taking antipsychotic medication is difficult to remember (reverse scored), and (4) I feel supported by my social network to take antipsychotic medication. Higher scores reflect more positive attitudes toward taking medication influences.

Psychosocial Functioning

The Quality of Life Scale (QLS)⁴⁸ was used to assess functional outcomes including social and role functioning. The QLS is a commonly used 21-item, semi-structured interview comprised of four subscales: intrapsychic foundations, interpersonal foundations, instrumental functioning, and common objects and activities as well as a total score.

Statistical Analyses

We first examined the associations between insight and demographic and diagnostic characteristics in the full sample with Pearson's correlations for continuous variables and *t*-tests or one-way analyses of variance for categorical variables. To evaluate whether participants who are in NAVIGATE differed from CC in changes in insight over the 2-year study period, we conducted a three-level mixed-effects linear regression model using the same approach as Kane et al. (2016), with changes in the PANSS insight scores from baseline to the four follow-up assessments (6, 12, 18, and 24 months) as the dependent variables, and treatment group, time, and their interactions as the independent variables, including gender, size, and student status as covariates. We included all timepoints in the analysis and linearized the time variable using a square root transformation²⁶ as the largest treatment effects were previously shown to occur in the first 6 months, with effects generally leveling off following this. Multilevel modeling was used in this analysis given the nested structure of the data and models were fit with random intercepts and slopes for the time at the individual and site level. Analyses were conducted using R Studio (Version 1.2.5) and missing data were accounted for using Restricted Maximum Likelihood.

We next evaluated the associations between insight and the other outcome variables (clinical and psychosocial functioning, subjective experience) at baseline by

computing Pearson’s correlations in the total sample. Then, to explore whether the NAVIGATE program influenced the associations between insight and the outcome variables differently than CC, we computed Pearson’s correlations at the 6-month assessment separately within each of the treatment groups. To determine whether the strength of correlations between insight and the other outcome variables at 6 months differed significantly between the 2 interventions, we computed Fisher’s *r* to *Z* transformations.

We conducted two post hoc analyses to better understand whether the finding from the previous analysis that insight was significantly more strongly correlated with quality of interpersonal relationships (on the QLS) at 6 months for the NAVIGATE group than the CC group. Since the NAVIGATE intervention was more effective than CC at improving both insight and overall symptom severity, as well as interpersonal relationships,²⁶ these analyses explored whether the increased association between interpersonal relationships and insight in the NAVIGATE group was unique to insight or could be explained by similar increases in the association between relationship quality and other dimensions of psychopathology. First, we computed correlations between QLS interpersonal relationships and the PANSS total score (dropping the lack of insight item) along with the PANSS subscales at baseline for the combined sample, and at 6-month separately for each group, and computing Fisher’s *r* to *Z* transformations to test differences in the magnitude of correlations between the groups at 6 months. Second, we evaluated whether improvements in interpersonal relationships and reductions in lack of insight and other dimensions of psychopathology over the first 6 months were more strongly associated in the NAVIGATE group than CC by computing correlations between change scores for these variables separately for the two groups and testing the difference in correlations by computing Fisher’s *r* to *Z* transformations.

Results

Two demographic variables were significantly associated with impaired insight. Participants who were current students had more intact insight than those who were not (*t* = 2.05, *P* = .041), whereas participants who were living at home had less insight than those living elsewhere (*t* = -2.54, *P* = .012). DUP was not related to lack of insight at baseline. A one-way ANOVA comparing schizophrenia, schizoaffective disorder, and schizophreniform disorder on insight was not significant. Lifetime alcohol use was not related to insight at baseline, although there was a marginally significant association between lifetime cannabis use disorder (measured on the SCID as none, subclinical, and clinical) and more impaired insight (χ^2 = 17.87, *P* = .057).

Treatment Effects on Insight

For the multilevel regression model including all timepoints, there was a significant effect of time (*P* < .001) and a significant interaction between time and treatment group (*P* < .001) (see table 2 for full details of the model). The results did not change when covariates were excluded from the analysis. The interaction reflected a significantly greater reduction in lack of insight over the study period for the NAVIGATE group than CC, which is depicted in figure 1. Most of the improvement in insight in NAVIGATE occurred during the first 6 months of the study, with more gradual gains over the following 18 months, compared to CC which did not change at all from baseline.

Symptoms, Functioning, and Subjective Experience Correlates of Insight

Insight at baseline was significantly correlated with all of the outcome measures except stigma. Lack of insight was associated with less severe depression (on both the PANSS and CDSS) and better well-being, but with more severe symptoms on the other PANSS subscales and worse functioning on the total QLS and all its subscales,

Table 2. Random and Fixed Effects For Predicting Positive and Negative Syndrome Scale (PANSS) Insight

Fixed Effects	Estimate	St. Error	<i>t</i>	<i>P</i>
Intercept	4.00	0.15	26.80	<.001
Gender	-0.06	0.10	-0.63	.53
Student status	-0.24	0.11	-2.15	.03
Treatment group	-0.12	0.13	-0.93	.35
Time	-0.09	0.02	-4.70	<.001
Treatment group: Time	0.09	0.03	3.01	<.001
Random effects	Estimate	SD		
ID: Site (intercept)	0.45	0.67		
ID: Site (intercept)	0.83	0.17		
Site (time)	0.83	0.91		

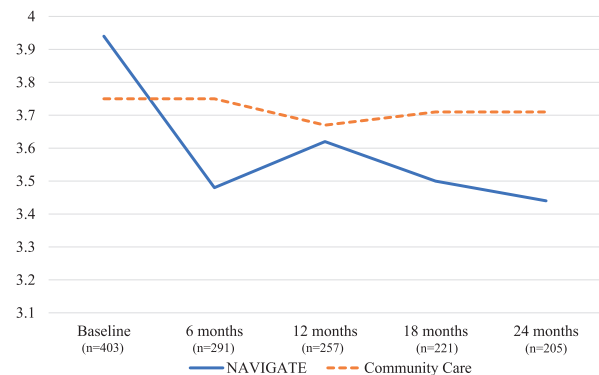


Fig. 1. Impaired insight on the PAANSS over time by treatment group.

Table 3. Impairments in Insight at Baseline and Six Month Correlates with Corresponding Demographic, Clinical, and Functional Variables

	Baseline Insight Impairment <i>r</i>	6-Month Insight Impairment		<i>r</i> to <i>Z</i> <i>Z</i>
		CC <i>r</i>	NAVIGATE <i>r</i>	
PANSS	.342**	.469**	.460**	.090
Negative	.175**	.182**	.305**	-1.027
Positive	.247**	.480**	.411**	.676
Disorganization	.292**	.373**	.358**	.373
Excited	.170**	.383**	.195*	1.616
Depression	-.132**	-.152	-.039	-8.95
Quality of Life Scale	-.287**	-.247**	-.388**	1.233
Intrapsychic Foundations	-.266**	-.251**	-.393**	1.246
Interpersonal Relationships	-.238**	-.190*	-.412**	1.927*
Common Objects	-.131**	-.100	-.182*	.700
Role Functioning	-.179**	-.169*	-.171*	.017
Stigma	-.081	-.072	.094	1.013
Well-being	.133*	.157	-.085	1.910*
CDSS	-.144**	-.159	.034	1.524
Medication Beliefs	-.129*	-.141	-.297**	1.330

Note:

* = $p < .05$;

** = $p < .01$; CC= Community Care; PANSS = Positive and Negative Syndrome Scale; CDSS = Calgary Depression Scale for Schizophrenia

as well as lower beliefs about the helpfulness of medication. These correlations are presented in table 3.

Symptoms, Functioning, and Subjective Experience Correlates at 6 Months

The correlations between lack of insight and the other outcomes at 6 months for the CC group were similar to those seen at baseline in the full sample (table 3). For the NAVIGATE group, on the other hand, several correlations were different. Specifically, Fishers *r* to *Z* transformations indicated that at 6 months compared to CC, insight was significantly *less* strongly correlated with well-being in NAVIGATE, but significantly *more* strongly correlated with interpersonal relationships. Better insight into the illness was more strongly related to worse well-being in the CC group than in the NAVIGATE group at 6 months, whereas better insight was more strongly related to better relationships in NAVIGATE than in CC.

The post hoc analyses examining the correlations between symptom severity on the PANSS and interpersonal functioning on the QLS at 6 months within each of the treatment groups indicated that less severe symptoms (overall and specific subscales) were associated with better social relationships within each of the groups, with no differences between the groups in the strength of any of the correlations (see table 4). Reductions in different dimensions of symptom severity tended to be

correlated with improvements in interpersonal relationships in both treatment groups. However, Fisher's *r* to *Z* transformations indicated that two of the correlations in change scores were significantly different between the two groups. First, improvement in insight was significantly correlated with improvement in interpersonal relationships in NAVIGATE but not in CC. Second, improvement in PANSS depression was significantly correlated with improved interpersonal relationships in CC but not NAVIGATE. Relatedly, the difference between treatment groups in the correlation between changes in the CDSS and relationships was marginally significant, with reductions in depression being correlated with improved interpersonal relationships in the CC group but not NAVIGATE.

Discussion

Participants in the NAVIGATE program, an EIS for persons with FEP, improved significantly more in clinical insight into their illness on the PANSS insight and judgment item than their counterparts (CC) who received usual care. Most of the gains occurred during the first 6 months of the program, with some additional gains over the remaining 18 months. In contrast, participants in CC showed no change in lack of insight from their baseline levels over the 2-year study period, despite improving in all of the symptom subscales of the PANSS over the follow-up period.²⁶

Table 4. Correlations between the Positive and Negative Syndrome Scale (PANSS) and Interpersonal Relationships on the Quality of Life Scale across both Treatment Groups

	Baseline Interpersonal Relationships		6-Month Interpersonal Relationships		<i>r</i> to <i>Z</i>
	<i>r</i>	<i>r</i>	CC	NAVIGATE	
			<i>r</i>	<i>r</i>	
PANSS	-.456**	-.524**	-.610**		1.061
Negative	-.441**	-.488**	-.613**		1.505
Positive	-.239**	-.256**	-.301**		.407
Disorganization	-.278**	-.402**	-.375**		-.266
Excited	-.139**	-.115	-.213**		.842
Depression	-.072	-.278**	-.151		-1.114
Lack of insight	-.238**	-.190*	-.412**		1.927*
CDSS	-.167**	-.202*	-.157*		-.388
		Change in Interpersonal Relationships from Baseline to 6-Months			<i>r</i> to <i>Z</i>
		CC	NAVIGATE	<i>Z</i>	
Change in PANSS from Baseline to 6-Months		-.372**	-.455**		.837
Negative		-.352**	-.467**		1.157
Positive		-.191*	-.282**		.806
Disorganization		-.165	-.230**		.567
Excited		-.127	-.089		-.321
Depression		-.314**	-.068		-2.145*
Lack of insight		-.133	-.355**		1.982*
CDSS		-.280**	-.097		-1.59

Note:

* = *p* < .05;

** = *p* < .01; CC= Community Care; PANSS = Positive and Negative Syndrome Scale; CDSS = Calgary Depression

Previous research has shown that people with FEP during an acute episode do improve in insight following pharmacological treatment, but these gains usually occur relatively soon after beginning treatment.²⁰ For example, one study tracked changes in insight in an FEP population over 1 year and found the most pronounced improvement in insight occurred 3 months after initiation of antipsychotic treatment, with few gains thereafter.⁴⁹ Participants were recruited into the RAISE-ETP study an average of 2 months following their index hospitalization (for the 58.7% of participants who enrolled following a hospitalization), and thus the lack of change in insight in the CC group may be due to the fact that the beneficial effects of antipsychotic medication on insight may have occurred prior to completion of the baseline assessments for the study participants.

Previous randomized controlled studies of EIS programs similar to NAVIGATE have not reported the effects of interventions on the insight.²³ One somewhat different program for FEP did report beneficial effects of comprehensive intervention on improved insight. In a randomized controlled trial with 1268 early stage (within the past 5 years) schizophrenia patients, Guo et al. (2010)⁵⁰ reported that participants who received a program provided one day per month over 12 months which included pharmacological treatment

plus psychoeducation, family intervention, social skills training, and cognitive behavior therapy improved more in clinical insight over the year than participants who received pharmacological treatment alone. Improvements in insight both for participants in the NAVIGATE program and those receiving comprehensive treatment in the Guo et al. study may be due to the common elements of psychoeducation provided in both programs. There is growing evidence that psychoeducation about the nature of psychosis and its treatment can have beneficial effects on improving insight into the illness^{2,17,51} as well as treatment adherence.⁵² This study's findings that impaired insight was associated with lower beliefs that medication will be helpful is also in line with prior research on insight, attitudes toward medication, and medication adherence.^{53,54}

Similar to previous research on both FEP and multiepisode schizophrenia populations,^{9,10,19,20} the present study found that higher levels of clinical insight at baseline were associated with less severe psychotic, negative, disorganized, and excited symptoms, and better psychosocial functioning, but more severe depression and worse well-being. This "paradox" of insight into the illness being related to better functioning and less severe symptoms, but worse subjective experience, has been frequently discussed in the literature.¹⁵⁻¹⁷ While similar

associations between insight and both depression and well-being were found at the 6-month assessment for participants in CC, among those in NAVIGATE better insight was no longer significantly associated with either worse depression or lower well-being.

There are several reasons why NAVIGATE may have fostered insight into the illness without worsening depression or well-being. First, the overall NAVIGATE program was aimed at supporting self-determination and imbuing hope through the identification of and work toward individual participants' goals, which often included completing their education, finding or maintaining work, and developing close relationships.²⁴ This focus may have averted the loss of hope associated with understanding the nature of one's psychiatric illness, which has been found to mediate the effects of insight on depression and well-being.¹³ Second, psychoeducation was provided in both the family education and IRT components of the NAVIGATE program to provide a positive, recovery-oriented perspective on psychosis, and to avoid negative, "spirit-breaking" messages⁵⁵ about the illness and its effects on people's lives. This positive approach may have minimized untoward effects of psychoeducation on improving insight at the cost of worsening mental health well-being, as has been reported in some studies.^{2,56} Third, the IRT component of NAVIGATE included a specific module on "Processing the Psychotic Episode," which was aimed at helping individuals develop a personally meaningful narrative about their experience with psychosis to facilitate moving forward with their lives and their goals. As a part of teaching this module, self-stigmatizing thoughts and beliefs that participants had about psychosis were explored, and when present, were actively disputed through the teaching of cognitive restructuring.^{24,27} Self-stigma about psychosis has been hypothesized to be an important mediator of the effects of insight into the illness and lower mental health well-being.⁵⁷⁻⁵⁹ Fourth, for individuals who had significant symptoms of depression, two additional modules in IRT could be provided, including the "Dealing with Negative Feelings" and "Coping with Symptoms" modules. The skills taught in these modules may have further minimized any effects of increasing insight on worsening dysphoria.

The effects of the NAVIGATE program on improving insight without worsening depression and well-being may be shared by other EIS programs that incorporate similar treatment components. For example, among participants in the EIS program developed by Addington and Addington (2001),⁶⁰ impaired insight at baseline on the PANSS was significantly correlated with more severe positive symptoms, negative symptoms, and general symptoms, but less severe depression on the CDSS. However, at the 1-, 2-, and 3-year assessments, following improvements in insight, impaired insight was no longer significantly related to depression, while it continued to be related to the severity of other symptoms.⁶¹

Aside from the difference between NAVIGATE and CC participants in the associations between insight and depression and well-being at the 6-month assessment, impaired insight was correlated to a similar degree with more severe other symptoms and reduced functioning in most areas between the 2 groups, with one exception: lack of insight was significantly more strongly correlated with the quality of social relationships on the QLS in participants in NAVIGATE ($r = -.412$) than CC ($r = -.190$). As impaired insight may reflect the overall severity of the illness,⁶² we explored whether the difference in associations between insight and social relationships between the two groups at 6 months also existed for other symptoms. However, it did not: the severity of other symptoms tended to be correlated with worse social relationships in both groups, with no significant differences between the groups. Examination of the correlations between changes in social relationships and changes in lack of insight and other symptoms over the first 6 months for the two groups provides further evidence for the importance of insight into the illness. Although reductions in most of the symptom dimensions tended to be more strongly correlated with improvements in social relationships in NAVIGATE than in CC, the difference was significant only for the correlation between improved insight and relationships ($r = -.355$ vs $-.133$, respectively). Thus, the association between clinical insight and social relationships became significantly stronger over time for the NAVIGATE group than the CC group, and the correlation between changes in insight and relationships was significantly stronger in NAVIGATE than CC, in contrast to all of the other symptom dimensions or overall symptom severity.

The findings indicate that the association between insight into having a psychiatric illness and the quality of social relationships was strengthened in the context of a treatment program (NAVIGATE) that targeted and improved both outcomes. These results raise the possibility that insight and social relationships interacted synergistically over time in response to treatment, with changes in one contributing to changes in the other. For example, improvements in insight may have contributed to better social relationships as individuals' self-perceptions became more aligned with the perceptions of others, creating a stronger basis for a shared reality within relationships. Gains in the quality of social relationships could have also contributed to improved insight as individuals became closer to and trusted more people, and became more willing to consider their divergent viewpoints, including their perspectives about the individual's psychiatric illness. In line with this, Koren et al. (2013)⁶³ reported that most of the improvement in insight over the first 6 months of FEP participants in an EIS program occurred due to gains in secondary awareness of the illness, or the ability to appreciate that one's self-perception is at odds with others. Thus, helping individuals who are

recovering from an FEP develop deeper and more meaningful social relationships, including enhancing their capacity to understand others' perspectives (ie, theory of mind), may foster improved insight into their illness.

One significant limitation of this study was the use of a measure of insight based on a single rating (from the PANSS). For example, the use of a more robust measure of insight, such as the Scale to Assess Unawareness of Mental Disorder (SUMD),⁶⁴ which distinguishes between insight into the illness, symptoms, treatment response, and social consequences, or the BIS,³⁴ which provides a subjective perspective on insight, could have shed more light on the understanding of which dimensions of insight are most strongly correlated with depression (at baseline) and social relationships (at 6 months), which were most sensitive to treatment-related change in the NAVIGATE program. However, we note that the lack of insight item on the PANSS has been shown to be significantly correlated with other measures of clinical insight,³³⁻³⁵ has been used in many other large clinical trials,^{49,52,65} and was associated with other symptoms and measures of functioning at baseline in this study in a similar way to numerous other studies. Further research is needed to understand the interplay between different dimensions of insight, symptoms, and functioning, and response to EIS treatment in persons recovering from an FEP.

Supplementary Material

Supplementary material is available at <https://academic.oup.com/schizophreniabulletin/>.

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Drs. Meyer-Kalos and Gingerich are national trainers for the NAVIGATE model. All other authors have no existing conflicts.

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