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Recovery After Initial Schizophrenic Episode – Early Treatment Program (RAISE-ETP)

National Institute of Mental Health (NIMH) Study: Recovery After an Initial Schizophrenia Episode (RAISE)

- N = 404
- Age: 15-40 years
- Diagnoses: schizophreniform disorder, schizophrenia, schizoaffective disorder, psychotic disorder NOS, acute psychotic disorder
- < 6 months antipsychotic treatment
- Cluster randomized assignment of 34 centers to integrated care (NAVIGATE) or community care
- Treatment and follow-up for >/=2 years
- Primary outcome: quality of life
- Secondary outcomes: service utilization, cost, subjective well-being, relapses, hospitalization, recovery, cardiometabolic health

NIMH, National Institute of Mental Health; NOS, not otherwise specified.

1. Kane JM et al. *J Clin Psychiatry*. 2015;76(3):240-6.

NAVIGATE vs. Community Care

- NAVIGATE is a comprehensive coordinated specialty care (CSC) program for first episode psychosis[1]
  - Team based
    - Shared decision-making
    - Strength & resiliency focus
    - Psychoeducational teaching skills
    - Motivational enhancement teaching skills
    - Collaboration with natural supports
  - Four components of NAVIGATE
    - Psychopharmacology – COMPASS
    - Individual Resiliency Training (IRT)
    - Family psychoeducation
    - Supported employment/education
- Community Care[2]
  - Psychosis treatment determined by clinician choice and services availability
  - Sites received no additional training or supervision except for guidance regarding subject recruitment, retention, and collection of research data

1. Mueser KT *Psychiatr Serv*. 2015; 66(7):680–690.
2. Kane JM et al. *J Clin Psychiatry*. 2015;76(3):240-6.

RAISE Demographics: Adjusted for Cluster Design

	NAVIGATE	Community Care	P Value
Age and Gender			
Age (mean)	23.18	23.08	
Males (%)	78	66	.05
Race			
White (%)	62	44	
African American (%)	28	49	
Other (%)	7	10	
Role Functioning			
In school (%)	16	26	.03
Working (%)	13	17	
Prior Hospitalization (%)	76	81	.05

RAISE, Recovery After an Initial Schizophrenia Episode.

1. Kane JM et al. *Am J Psychiatry*. 2016;173(4):362-72.

Prevalence of Metabolic Dysregulation in Patients With First-Episode Psychosis—RAISE-ETP Study

- Patients aged 15–40 years* diagnosed with schizophrenia or related disorders† treated with <6 months of cumulative antipsychotic use (N = 394‡)

Variable	Number (%)
Weight (n = 389)	
Obese	86 (22.1)
Overweight	102 (26.2)
Dyslipidemia (n = 286)	161 (56.5)
Blood pressure (n = 389)	
Prehypertension, blood pressure 120-139/80-89 mm Hg	155 (39.9)
Hypertension, blood pressure ≥140/90 mm Hg	39 (10.0)
Metabolic syndrome, fasting glucose ≥100 mg/dL per ATP III (n = 257)	34 (13.2)
Prediabetes	
Glucose-based, 100-125 mg/dL (n = 101)	4 (4.0)
HA_{1C}-based, 5.7%-6.4% (n = 280)	43 (15.4)
Diabetes	
Glucose-based, >125 mg/dL (n = 101)	3 (3.0)
HA_{1C}-based, >6.4% (n = 280)	8 (2.9)
Smoking (n = 394)	200 (50.8)

Mean age: 23.6 years

Mean lifetime antipsychotic exposure: 47.3 days

*One patient was 51 years old.

†Related disorders included schizophreniform disorder, schizoaffective disorder, psychotic disorder not otherwise specified, or brief psychotic disorder.

‡Enrolled patients with cardiometabolic data.

ATP III, National Cholesterol Education Program Adult Treatment Panel; HA_{1c}; glycosylated hemoglobin.

1. Correll CU et al. *JAMA Psychiatry*. 2014;71(12):1350-1363.

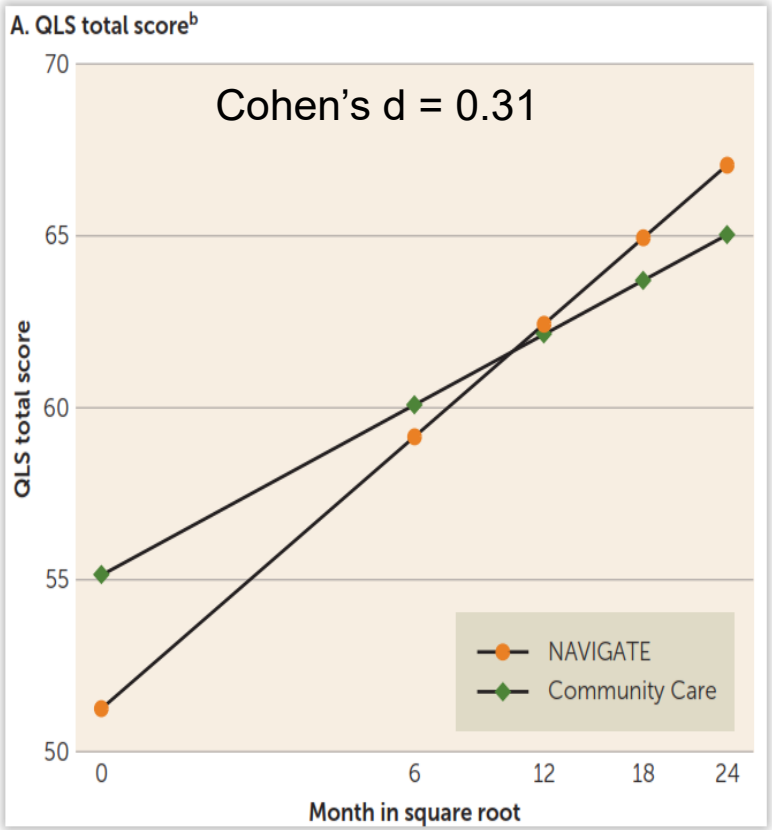
Recovery After an Initial Schizophrenia Episode-Early Treatment Program (RAISE-ETP): 2-Year Findings

- Over 2 years of treatment, compared to patients who received community care, those who received NAVIGATE:
  - Remained in treatment longer ($p<0.004$)
  - Were more likely to have received mental health outpatient services each month ($p=0.013$)
  - Demonstrated greater improvement on the:
    - Quality of Life Scale total score ($p<0.02$)
    - Positive and Negative Syndrome Scale (PANSS) total score ($p<0.02$)
    - PANSS depression factor ($p<0.05$)
    - Calgary Depression Scale for Schizophrenia ($p<0.04$)

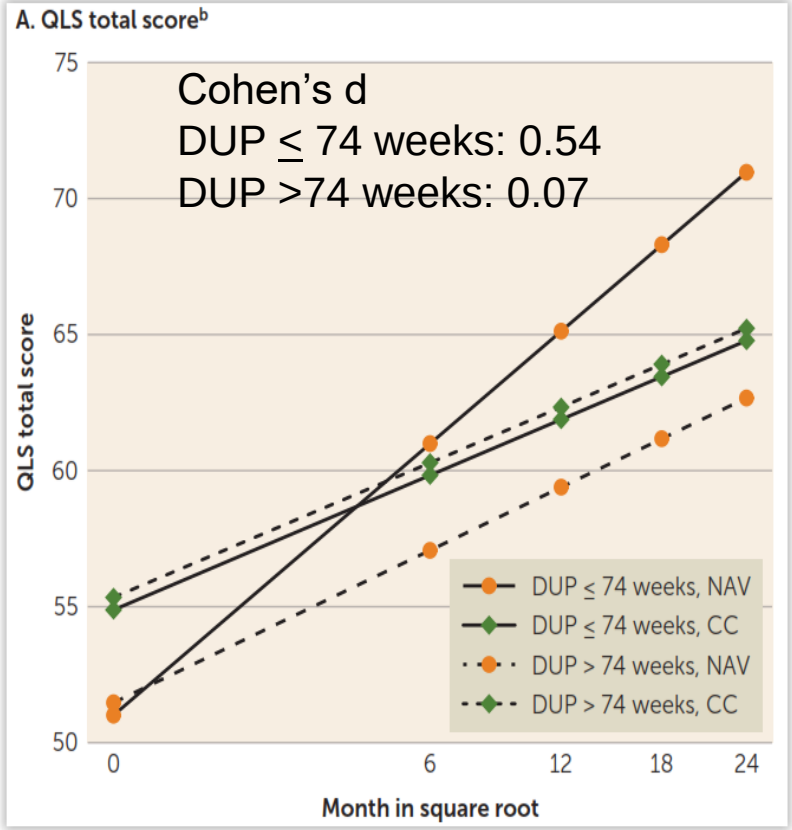
1. Kane JM et al. *Am J Psychiatr*. 2016; 173(4):362-372.

Quality of Life Scale Fitted Model

Group by Time Interaction (p= 0.015)



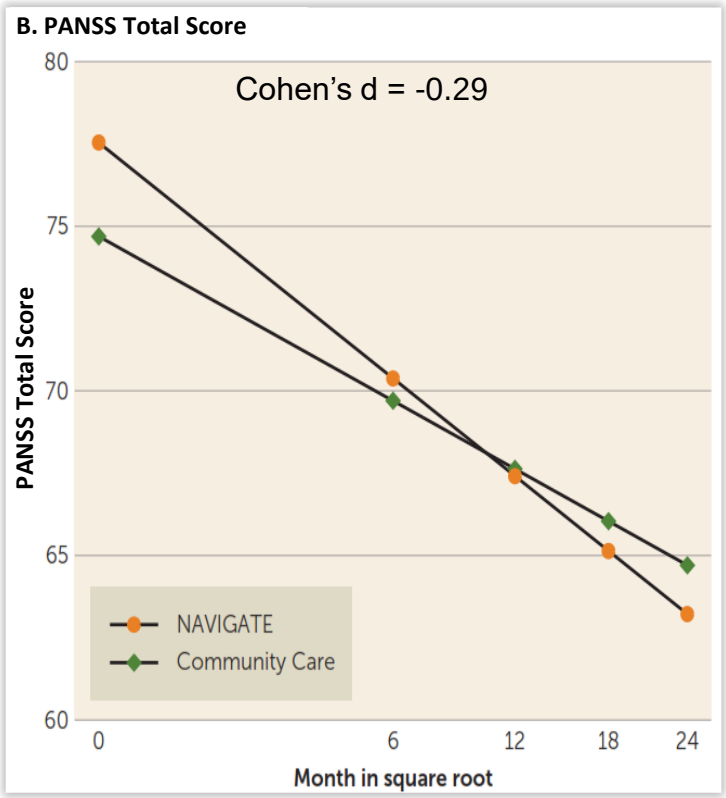
Duration of Untreated Psychosis (DUP) by Time Interaction (p= 0.003)



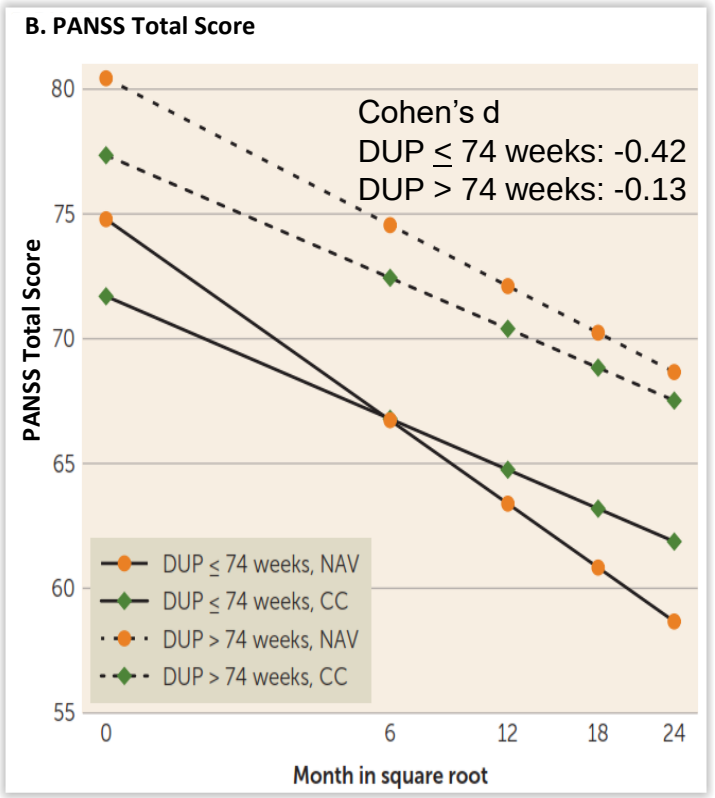
1. Kane JM et al. *Am J Psychiatry*. 2016; 173(4):362-72.

RAISE: PANSS Total Score Change Over 2 Years

Group by Time Interaction (*P* = 0.016)



DUP by Time Interaction (*P* = 0.043)



Median DUP = 74 weeks

CC, Community Care, DUP, duration of untreated psychosis; NAV, NAVIGATE; PANSS, Positive and Negative Syndrome Scale, RAISE, Recovery After an Initial Schizophrenia Episode.

1. Kane JM et al. *Am J Psychiatry*. 2016;173(4):362-72.

Recovery After an Initial Schizophrenia Episode-Early Treatment Program (RAISE-ETP): Psychopharmacologic Treatment Outcomes

- NAVIGATE patients as compared to Community Care patients:
  - Gained less weight ($p<0.001$)
  - Experienced fewer side effects ($p=0.002$[a])
  - Were more likely to receive an LAI (OR=1.45[b])
- NAVIGATE patients were also:
  - More likely to receive an antipsychotic (OR=3.73; p=0.005) and those prescriptions were more likely to conform to NAVIGATE prescribing principles (OR=2.19; p=0.037)
  - Less likely to receive an antidepressant (OR=0.39; p=0.037)

Other vital signs and cardiometabolic laboratory findings did not differ between groups. Nevertheless, given the likely future duration of antipsychotic exposure, such differences are potentially important

[a]The model included treatment condition, time, and the treatment-by-time interaction; treatment-by-time interaction, F=3.86, df=5, 1143, p=0.002.

[b]Differences in LAI use were not statistically significant (p=0.645).

[c] Odds ratios greater than 1 indicate a greater likelihood of antipsychotic or antidepressant prescriptions at NAVIGATE sites; ratios less than 1 indicate a greater likelihood of antipsychotic or antidepressant prescriptions at community care sites.

LAI, long-acting injectable.

1. Robinson DG, et al. *Am J Psychiatry*. 2018; 175(2): 169-179.

Recovery After an Initial Schizophrenia Episode-Early Treatment Program (RAISE-ETP): Autonomy Support and Quality of Life

- Patients with first episode psychosis were divided into NAVIGATE (n = 223) or community care (n = 181) treatment groups
- PANSS, QLS, and the six-item Autonomy Support Scale were administered at baseline and in regular intervals over 24 months
- Patients in the NAVIGATE group:
  - Indicated an increase in perceived autonomy support over time, whereas no change was seen in patients receiving community care
  - An increase in perceived autonomy support was associated with improved quality of life scores and improved symptoms, regardless of treatment plan
- These findings are consistent with the NAVIGATE treatment model, which emphasized supporting client self-determination and autonomy

PANSS, positive and negative syndrome scale; QLS, quality of life scale.

1. Browne J et al. *Psychiatr Serv.* 2017 Sep 1;68(9):916-922. doi: 10.1176/appi.ps.201600480. Epub 2017 Jun 1.

RAISE-ETP Cost-effectiveness Analysis

- A study which used data from the RAISE-ETP study to evaluate cost-effectiveness of the NAV intervention (n = 223) vs. standard CC (n = 181) over 2 years utilized 3 strategies:
  - Mixed linear models: showed greater NAV effectiveness and greater total costs than CC
    - 26% of the increased costs attributable to increased outpatient service costs, 36% to greater medication costs, and 9% to additional training costs
  - Bootstrap analysis of ICERs: confirmed findings of greater benefits and cost for NAV
    - Greatest cost-effectiveness was observed among low-DUP clients and when generic drug prices were used
  - NHB: Found a 0.95 probability that NAV was more cost-effective than CC if the QLS-SD is valued at $40,000
    - Among low-DUP samples, there was a 0.94 probability that NAV was more cost-effective at only $20,000/QLS-SD*
    - Among the high-DUP patients there was a 0.31 probability at $20,000 and a 0.64 probability that NAV was cost-effective compared to CC at $50,000

In all analyses, NAV was more effective and more costly than CC, with greater cost effectiveness among low- vs high-DUP clients, and when generic drug prices were used for antipsychotics

*Effectiveness was measured as a one standard deviation change on the Quality of Life Scale (QLS-SD).

CC, community care; DUP, duration of untreated psychosis; FEP, first episode psychosis; ICER, incremental cost-effectiveness ratio; NAV, navigate intervention group; NHB, Net Health; Benefits; QLS-SD, Quality of Life Scale- one standard deviation; RAISE-ETP, Recovery After an Initial Schizophrenia Episode- Early Treatment Program.

1. Rosenheck R et al. *Schizophr Bull*. 2016;42(4):896-906.

Conclusions

- Coordinated Specialty Care (CSC) could be implemented successfully in real world clinics
- 2 years CSC intervention was superior to Community Care regarding QoL and all key secondary outcomes except for hospitalization risk
- Efficacy of CSC was moderated significantly by shorter duration of untreated psychosis, suggesting that outreach programs are needed to deliver CSC as early as possible