

RAISE Early Treatment Program: An RCT to Address CER Questions

Nina R. Schooler, Ph.D.
*Professor of Psychiatry & Behavioral
Sciences*
SUNY Downstate Medical Center
nina2277@msn.com

Disclosure of Commercial Interest

Type of affiliation

Commercial entity

Grant/research support

AstraZeneca

Bristol-Myers Squibb

Eli Lilly and Company

Janssen Pharmaceutica

Pfizer Inc

H. Lundbeck A/S

Consultant/advisory board

Abbott

Eli Lilly and Company

Hoffman-La Roche

OrthoMcNeil Janssen

H. Lundbeck A/S

Pfizer, Inc

Schering - a division of Merck

Recovery After an Initial Schizophrenia Episode

The NIMH RAISE Project

- Design and test effective interventions for early phase schizophrenia that can be implemented on a population-level basis
- Engineer rapid adoption and implementation of effective treatment packages by engaging “end users” at the start of intervention development
- Assess clinical, functional, and economic outcomes
- Generate information relevant to key stakeholders, including health care policy makers

RAISE Early Treatment Program

- John M. Kane, M.D. Principal Investigator
 - Feinstein Institute for Medical Research
- Collaborating institutions and investigators
 - SUNY Downstate Medical Center
 - ◇ Nina R. Schooler, PhD. PI
 - Dartmouth University
 - ◇ Kim Mueser, Ph.D. PI
 - University of North Carolina
 - ◇ David Penn, Ph.D. PI
 - Yale University
 - ◇ Robert Rosenheck, MD. PI
 - University of Calgary
 - ◇ Jean Addington, PhD. PI

Key CER Concepts that Inform RAISE ETP

- Study Populations Representative of Clinical Practice
- Focus on the Individual Rather Than the Average Patient
- Compare Two or More Interventions Directly
Comparison

How the Early Treatment Program Addresses RAISE goals and CER principles

- Establish Research Teams at 30 Community Sites
 - All teams provide first episode identification, engagement and strategies for retention
 - Team includes
 - ◇ Project director
 - ◇ Research assistant
 - NIMH funds support team and assessment
- Design Multi-dimensional psychopharmacologic and psychosocial treatment intervention - NAVIGATE
- Conduct RCT to Compare Community Care to NAVIGATE

Study Design

- Site Randomization to
 - Community Care
 - ◇ Recruitment
 - ◇ Engagement
 - ◇ Retention
 - ◇ Assessment
 - NAVIGATE - an enhanced treatment
- 400 subjects at 30 sites
- Treatment and follow-up for at least two years

NAVIGATE Characteristics

- Overall goal is Recovery – not management
- Team based – available at community settings
 - ◇ Program Director – family treatment provider
 - ◇ Psychiatrist /Nurse practitioner
 - ◇ 2 case manager level therapist
 - ◇ Supported employment/education specialist
- Shared decision-based model insures client involvement in treatment planning
- Interventions are manual driven
- Training and on-going supervision to insure fidelity

NAVIGATE COMPONENTS

- Psychopharmacologic treatment
 - Computerized Decision Support tailored for first episode schizophrenia
 - Provides measurement based treatment
- Family treatment
 - Basic psychoeducation
 - Module based - communication and problem solving
- Individual Resiliency Training
 - Goal oriented, module based and manual driven
- Supported employment/education

Critical Design Elements

- Site randomization
 - Statistical analysis based on cluster models
 - Personnel at sites know treatment
 - Informed consent to treatment does not require understanding of randomization
- Sites are inexperienced in research
 - Contributes to external validity
 - Threatens internal validity
 - ◇ Treatment implementation
 - ◇ Reliable diagnosis and outcome assessment

Trial Conduct Implications of Site Randomization and Site Characteristics

- Treatment implementation
 - Manual driven treatments
 - Central support for implementation and fidelity
 - Medication support system through Computerized Decision Support System
- Assessment of measures tied to primary outcomes
 - Centralized clinical assessors who are blinded to randomization and study design
 - Assessment via live two-way video connection

Outcome Assessment

- Quality of Life
 - Quality of Life Scale improvement is primary outcome
- Symptoms
- Service use and cost
- Work and school functioning
- Self assessment by clients and families

What Do we Expect to Learn

- Does NAVIGATE improve two year outcome compared to Community Care in terms of
 - Working
 - School
 - Social engagement with peers
 - Symptoms of psychopathology
 - Quality of life
- Are the benefits large enough to offset costs?

Review of Key CER Concepts that Inform RAISE ETP - I

- Study Populations Representative of Clinical Practice
 - Over 30 sites
 - Clinical settings include all regions of the country
 - Large and small urban, suburban . rural
- Focus on the Individual Rather than the Average Patient
 - Navigate is a multi-dimensional package
 - Tailoring to individual needs and goals
 - Choice is embedded

Review of Key CER Concepts that Inform RAISE ETP - II

- Compare Two or More Interventions Directly
 - NAVIGATE is experimental treatment
 - Community Care represents a range of available treatments
 - ◇ Allows for secular trends as Community Care changes if/when health care delivery changes