

RAISE Connection Program: An RCT to Address CER Questions

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Disclosure of Commercial Interest

Ortho McNeil Janssen: Investigator Initiated Research Project

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

The RAISE Connection Program

- Jeffrey Lieberman, MD Principal Investigator
 - Research Foundation for Mental Health
- Lisa Dixon, MD, MPH Co-Principal Investigator
 - University of Maryland School of Medicine
- Research Partners
 - Office of Mental Health, New York State (Michael Hogan, PhD., and Lloyd Sederer, MD)
 - Mental Health Authority, Maryland (Brian Hepburn, MD, Gale Jordan-Randolph, MD)
- Co-Investigators
 - Howard Goldman, MD, PhD, Susan Essock, PhD, Robert Drake, MD, PhD., Naihua Duan, Stephen Marder, MD, Cam Carter, MD, Robert Buchanan, MD, Matcheri Keshavan, MD, Gunvant Thaker, MD, Westat, Lin Sikich, MD, Keith Neuchterlein, PhD, etc.

Key CER Concepts that Inform RAISE CP

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

Study Design

- 1:1 Participant level randomization to Connection Team or Connection Partnership
- Sites receive support for first year of services.
- State partnership provides support for programming for subsequent years
- Study will be two years long for 370 participants
- Assessments every three months

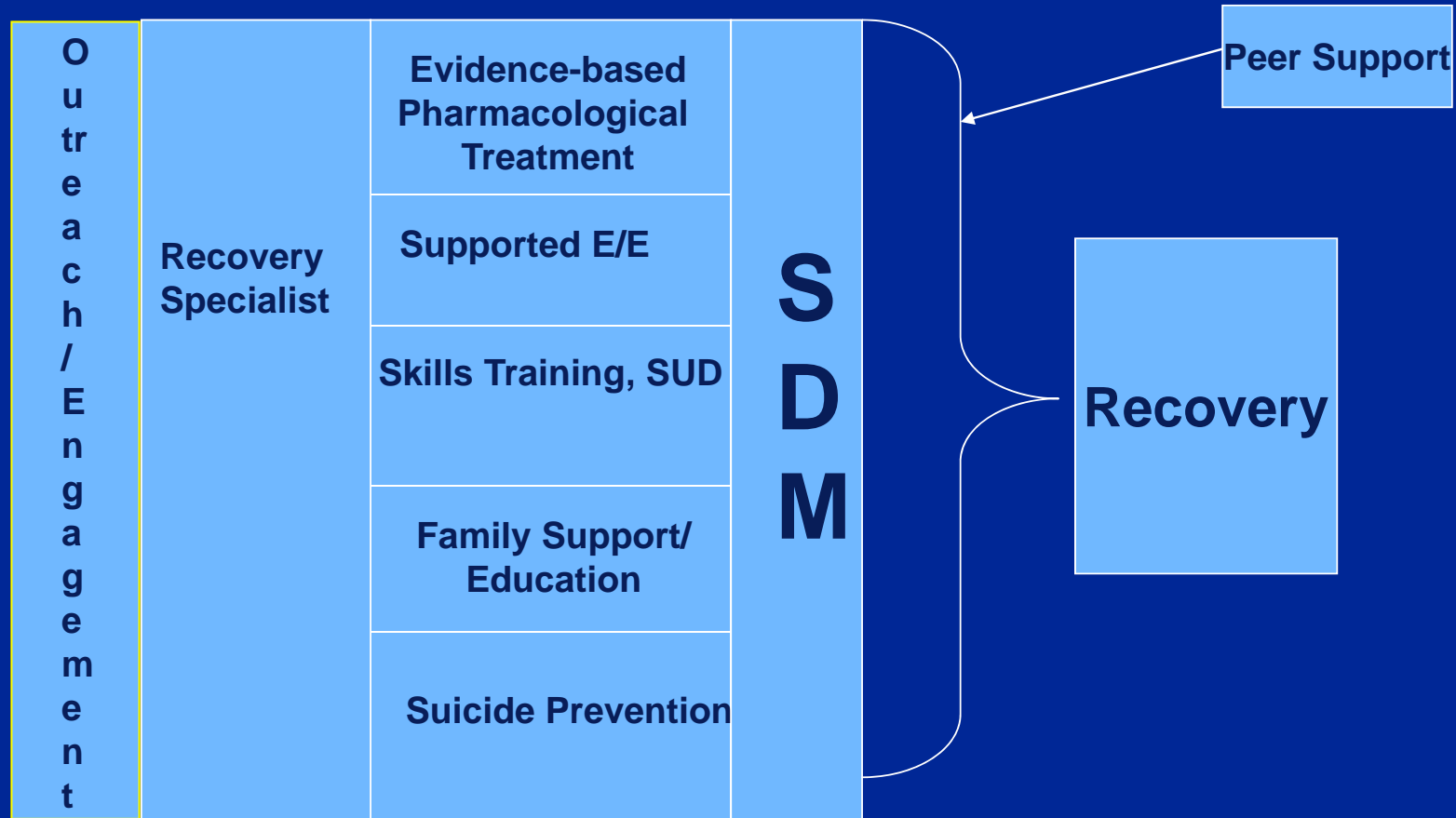
Connection Team Characteristics

- Overall goal is functional recovery – not management
- Team Leader, Recovery Specialist (Master's-level clinician)(1.0), Psychiatrist (0.2 FTE), Supported employment/supported education specialist (1.0 FTE), Skills training specialist (0.5 FTE)
- Interventions are manual driven
- Training and on-going supervision to insure fidelity. Supervision starts with experts and moves to state based trainers

Connection Team Key Elements

- Multi-element
- Team-based
- Grounded in notion of Critical Time Intervention Model
- Emphasis on outreach and engagement
- Shared decision making foundation of treatment decisions
- While clinic based, separated as much as possible from services for individuals with more chronic disorders

Connection Team Model



Connection Partnership

- **Manualized approach based on Critical Time Intervention Model**
- **Recovery-oriented care coordinator (0.5 FTE Master's Level Clinician)**
- **Training and on-going supervision to insure fidelity. Supervision starts with experts and moves to state based trainers**
- **Help engage participant, identify acceptable existing services and employing motivational approaches to facilitate engagement in such services**
- **Support for two years**

Outcome Assessment

- Functioning in work and school
- Social Functioning
- Symptoms
- Service use
- Self assessments by clients and families

What Do we Expect to Learn

- Does Connection Team improve two year outcome compared to Connection Partnership 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 Connections Program

- Study Settings and Populations Representative of Clinical Practice
 - Eight community sites that include suburban, rural and urban areas
 - Clinician training plan that emphasizes state level train the trainer model
 - Very broad inclusion criteria
 - Work directly with state mental health system to identify sites, consider outreach and recruitment, problem-solve funding, and conduct training

Review of Key CER Concepts that Inform RAISE Connection Program

- Compare Two or More Interventions Directly
 - Connection Team is experimental treatment
 - Connection Partnership represents a standardized modest increment over usual care that emphasizes engagement and assures that the best of usual care is made available
- Focus on the Individual: Connection Team and Connection Partnership can both be tailored to individual needs, goals and choice is embedded

Strengths and Challenges

- Patient level randomization increases internal validity but risks loss of individuals who will not agree to randomization and adds challenge of maintaining treatment integrity at sites
- Collaboration with states increases external validity in its engagement of public mental health system but limited to two states
- Choice of control gives stable comparator with some titration to usual care, but increases risk of finding of no difference