

Opportunity for Study of Early Phase Schizophrenia

RAISE – Recovery After an Initial Schizophrenia Episode

This study, funded by National Institute of Mental Health (NIMH), is a multi-site randomized controlled trial designed to evaluate the benefits of a comprehensive pharmacological and psychosocial treatment package (the RAISE Enhanced Treatment Program) for individuals with first episode psychosis compared to usual community mental health treatment (community care). In this study, all sites will be expected to engage individuals early in their first episode of psychosis and to recruit them into the study. Half of the sites will be randomized to provide the RAISE Enhanced Treatment program and the other half of the sites will be randomized to provide community care. All study participants will be assessed at baseline and every 6 months for at least 2 years via high technology video-based assessments by clinical evaluators who are blind to treatment assignment.

The program is led by Dr. John Kane at The Zucker Hillside Hospital in New York and colleagues from institutions including Dartmouth Medical School, University of North Carolina at Chapel Hill, Yale Medical School, University of Calgary, UCLA, and SUNY Downstate Medical Center. This document describes the overall RAISE project with the goal of helping agencies decide whether they may want to apply to be a research site.

Goals of RAISE Project

- To improve the long-term trajectory of schizophrenia and reduce its disability over the lifetime by providing rapid, comprehensive, effective treatment at the first episode of psychosis
- To develop and evaluate an intervention for first episode psychosis that can be delivered in a wide range of clinical settings and can be paid for primarily by existing funding mechanisms
- To compare the RAISE Enhanced Treatment intervention with community care in a rigorous, randomized controlled trial

Early identification and engagement into treatment

- All research sites will reach out into their communities to engage people who are experiencing new onset psychosis into treatment at their centers. These individuals with early psychosis will be invited to participate in the research study.
- All research sites will be expected to enroll approximately one first episode study participant each month over 16 months. Enrollment is expected to start in early 2010.

Resources and Benefits to All Participant Sites

- Being part of a national effort to improve the long-term trajectory and reduce disability of schizophrenia, currently the most severe and costly adult mental illness
- 20% MA level salary support for project management and outreach for recruitment for all sites
- 10% additional MA level salary support for Director role in sites randomized to provide RAISE Enhanced Treatment Program to defray cost of supervision and training
- A minimum of 5 hours/week support for the supported employment/education position or to facilitate the liaison between the RAISE Enhanced Treatment Director and an existing supported employment/education program
- 20% RA level salary support for research/coordination at all sites
- Reimbursement for research activities per participant enrolled in study (\$2000/participant)
- State-of-the-art videoconferencing equipment for use in the project
- Training in outreach, initial and continued engagement of first episode psychosis individuals and families
- Diagnostic information (based on research assessment) for all study participants will be provided to treatment providers

What is expected of sites assigned to Community Care?

- Recruitment of first episode research participants into the study
- Research participants will be offered all the usual and appropriate services available at the agency
- Training in the RAISE enhanced program will be available after completion of the study

What is expected of sites assigned to RAISE Enhanced Treatment?

- Recruitment of first episode research participants into the study
- Each site will form a clinical RAISE Enhanced Treatment team (not full time) to provide the intervention to research participants at their site (see below for description of RAISE team)
- The clinical staff for the RAISE team at the site will participate in initial training and regular consultation to learn the skills to deliver the RAISE Enhanced Treatment Program components, including:
 - Individual resiliency training
 - Supported employment/education
 - Family psychoeducation
 - Computer supported psychopharmacologic treatment and medical management

Eligibility Criteria for a Community Mental Health Center to Participate in RAISE

- Center provides psychosocial and medication community mental health services to individuals with psychotic illnesses including schizophrenia
- Center does not provide specialized first episode psychosis treatment
- Anticipated flow of at least 1 first episode psychosis individual per month during the 16 month recruitment period
- Sufficient staffing to fulfill the RAISE staff roles
- Willingness to implement the RAISE program and structure with high level of administrative support
- Meeting space to conduct research interviews, and meet with study participants and family members/significant others

Overview of the RAISE Enhanced Treatment Program

- The RAISE Enhanced Treatment Program is team-based and devoted to providing a comprehensive, individualized, and developmentally appropriate intervention for the first episode of psychosis. It has been designed to be largely reimbursable through existing funding mechanisms.
- All the treatment elements in the RAISE Enhanced Treatment Program are driven by participants' personal goals
- The focus of RAISE Enhanced Treatment of first episode psychosis is on:
 - Taking a shared decision-making approach involving the participant, family, and RAISE team members to all treatment decisions
 - Improving functioning in work/school, social relationships and leisure time, and independent living
 - Increasing resiliency, sense of purpose, and quality of life
 - Reducing symptoms, relapses, and hospitalizations
- Treatment will be provided in an individualized fashion for up to 2 years

What are RAISE Enhanced Treatment Components?

- Regular collaborative treatment planning and follow-up
 - Includes individual, family (or other significant persons), RAISE treatment team
 - Conducted at baseline and every 6 months
- Individualized psychopharmacological and medical management
 - Individually tailored to participant's symptoms and preferences
 - Guided by medication algorithm
 - Assisted by computerized decision support system
 - Measurement-based assessment of therapeutic response and side effects
 - Medical management of side effects such as weight gain
- Individualized resiliency training (IRT)
 - Individual counseling designed to improve personal resiliency and facilitate progress towards personal goals
 - Weekly or less frequent meetings, based on participant preferences
 - Core module includes: assessment and goal setting, information about psychosis and its management, processing the experience of psychosis, developing a relapse prevention plan, and resiliency training
 - Additional modules selected using shared decision-making and based on participants' needs and goals, including:
 - Managing distress

- Coping with symptoms
 - Dealing with substance abuse
 - Improving social relationships and leisure activities
 - Improving health (e.g., smoking, weight control, exercise)
- Case management provided
- Family psychoeducation
 - Involves “family” as defined by participant
 - Participant included in family sessions
 - Family and participant both considered “members of the RAISE treatment team” with ready access to team members
 - Provides information about nature and management of psychosis, and the role of the family in helping the participant
 - Provides options for further work on communication and problem solving skills
 - Frequency and intensity of sessions is determined by family need and preference
 - Most sessions begin weekly and taper after 1-2 months
- Supported employment/education (SEE)
 - 1 RAISE team specialist focuses solely on work/school
 - Goal is to help individual return to school/work and to optimize performance there
 - Personal preference guides the goals of working with the SEE specialist
 - Emphasis is on competitive work in the community or enrollment in educational programs in the community
 - Rapid job search or re-enrollment in school rather than prolonged assessment
 - Most services provided in community, not clinic
 - Supports provided as needed after successful attainment of work or enrollment in school
 - Disability benefits counseling is provided

Research participants may access other services in addition to those offered by RAISE (e.g., peer support).

How will the RAISE Enhanced Treatment team be staffed?

5 community mental health center staff will provide the RAISE Enhanced Treatment as a team (effort will depend on total caseload):

- 1 Director
 - Conducts outreach to stimulate referrals to RAISE program
 - Engages participants and family members/significant others into RAISE program
 - Coordinates overall RAISE team, including running weekly RAISE team meetings and leading treatment planning/review meetings
 - Provides family psychoeducation
 - Supervises clinician providing supported employment/education
 - Supervises clinicians providing individual resiliency training
- 1 Psychiatrist
 - Provides psychopharmacological management
 - Monitors medical disorders
 - Coordinates treatment with the RAISE team
- 1 Supported employment/education (SEE) specialist
 - Provides SEE, based on the supported employment model, adapted for persons with a first episode of psychosis
 - Helps participants articulate and pursue personal goals related to work and school
 - Coordinates with other members of the RAISE team
- 2 Clinicians who provide individual resiliency training (IRT)
 - Provide individual IRT, with specific topic modules chosen collaboratively with participant
 - Help participants make progress towards personal goals
 - Provide case management
 - Coordinate treatment with the RAISE team

RAISE Enhanced Treatment Team Meeting and Supervision Structure

- Weekly 1 hour RAISE team meeting for all members (5 person hours/week)
- Weekly 1 hour group supervision of the 2 IRT clinicians by Director (3 person hours/week)
- Weekly 1 hour supervision of the SEE specialist by Director (2 person hours/week)
- Total staff meeting/supervision time: 10 person hours/week

Timeline

- Training in first episode recruitment, engagement and retention for Project Directors and Research Assistants at Community Care and Enhanced Treatment sites will be conducted in early 2010 at a central national meeting convened by the NIMH.
- Additional training for clinical teams at sites randomized to Enhanced Treatment will take place in early 2010 at regional meetings.
- Participant enrollment will begin immediately following training and will continue through mid 2011.
- All participants will be treated and assessed for at least two years following enrollment. The study will end at sites in mid 2013.
- The NIMH contract funding assures level of effort and salary support for the Project Director and Research Assistant through mid 2011; subsequent level of effort and support may vary depending on site recruitment and retention.