

# RA1SE

## Recovery After an Initial Schizophrenia Episode

A Research Project of the NIMH

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# Background

- The current paradigm for treating schizophrenia in the United States focuses on managing established illness and entrenched disability
- RAISE will test whether early, aggressive, and pre-emptive intervention can slow or halt clinical and functional deterioration in schizophrenia
- Improved functioning among individuals with schizophrenia may translate into significant cost savings for society

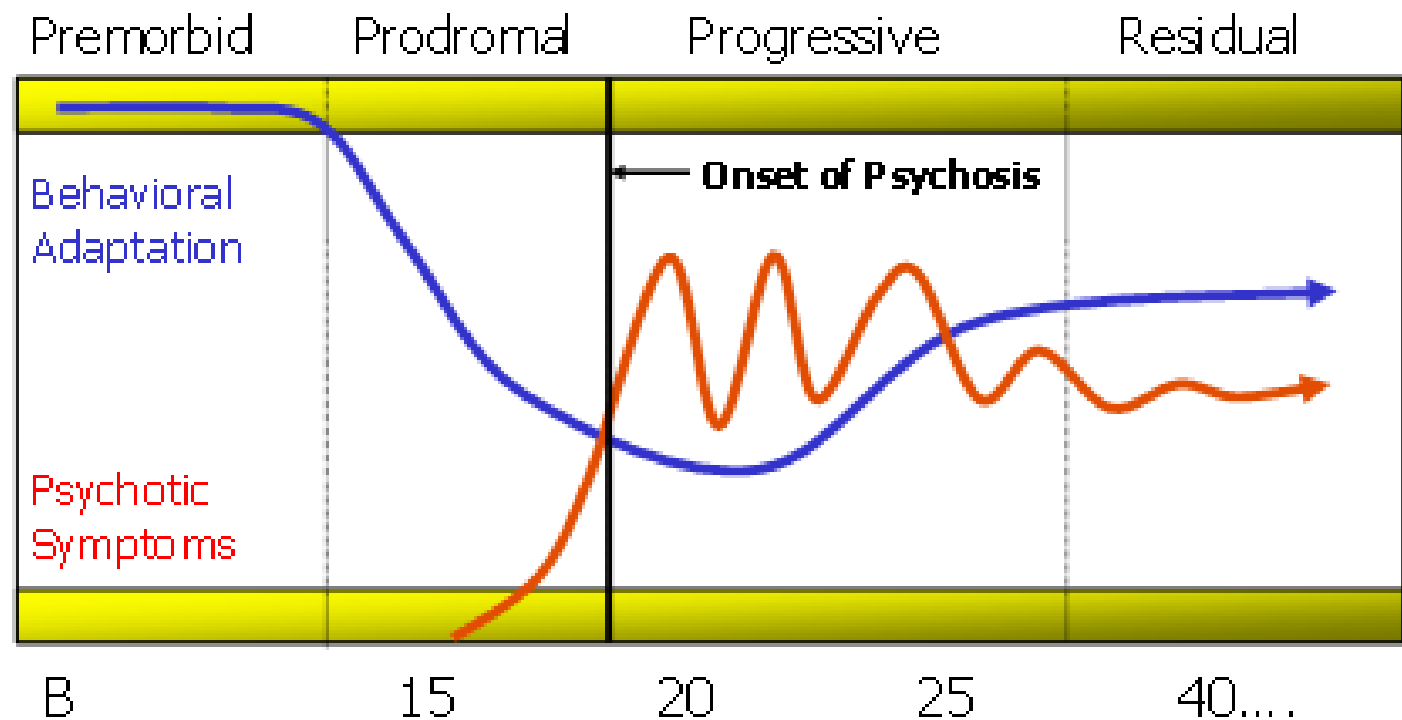


# Schizophrenia Facts

- Onset in late adolescence, early adulthood
- Psychotic symptoms, cognitive deficits, and social impairments contribute to disability
- Lifetime risk for suicide is ~5%
- ~2.5 million adults in U.S. are affected
- Economic cost of \$62.7 billion in 2002



# Clinical Course of Sz



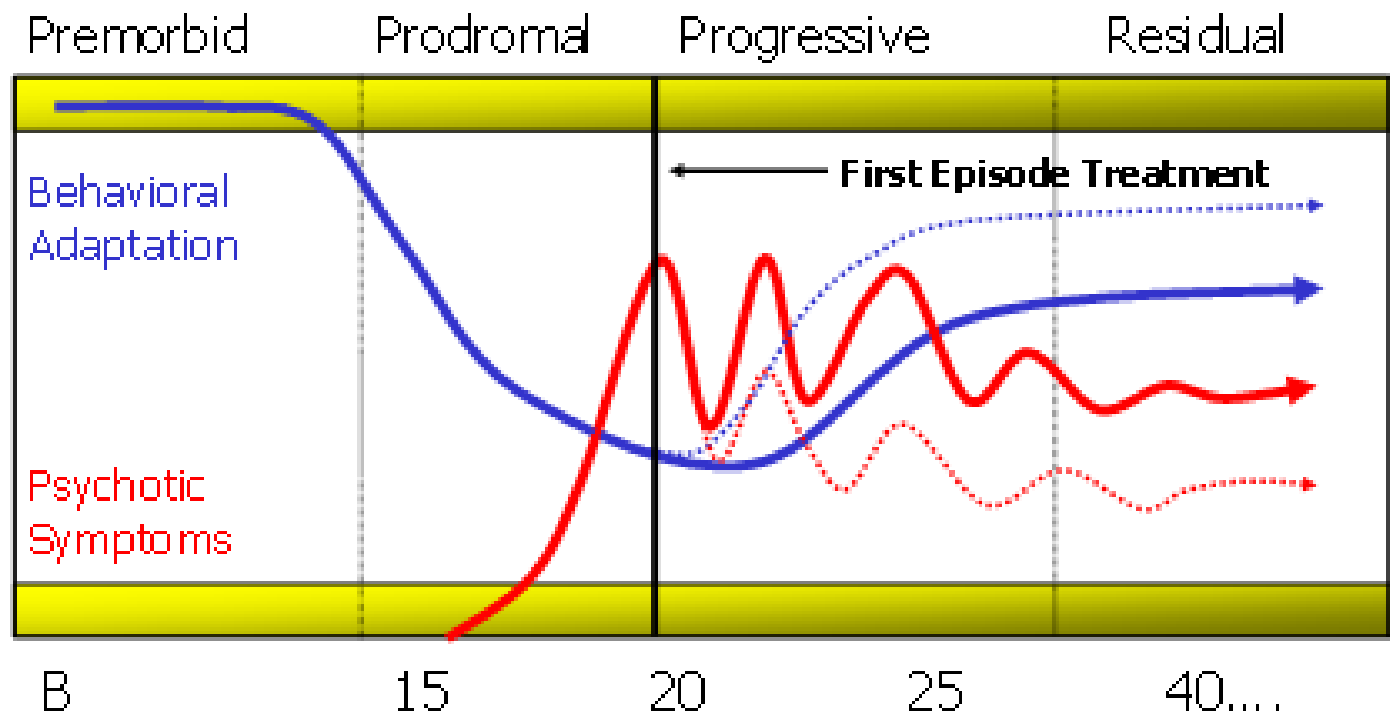
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# Improved Outcomes for 1<sup>st</sup> Episode Psychosis

- Earlier treatment produces better outcomes:
  - Better response to antipsychotic medications
  - Better outcomes for social and vocational rehabilitation
  - Greater impact for psychological therapies that target residual symptoms, behavioral adaptation, and quality of life



# Early Intervention Is Key



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# Projected Cost Savings

Outcome	Degree of Improvement	Annual Cost Savings
Reduced Unemployment	10%	\$2.5 billion
	25%	\$6.3 billion
Reduced Caregiver Burden	10%	\$0.9 billion
	25%	\$2.3 billion
Reduced Justice Involvement	10%	\$0.3 billion
	25%	\$0.8 billion
Reduced Homelessness	10%	\$0.7 billion
	25%	\$1.9 billion

Leslie, D.L., The economic burden of schizophrenia in the United States: A report prepared for the National Institute of Mental Health, 2007.



# RAISE Objectives

- 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



# Structure of Contracts

## Three Phase Project:

- Phase 1: Intervention development and refinement
  - *July 16, 2009 – Winter 2010*
- Phase 2: Feasibility testing of intervention
- Phase 3: Large scale practical clinical trial



# Project Teams

## **Feinstein Institute for Medical Research (FIMR)**

PI: John Kane, MD

- Zucker Hillside Hospital
- SUNY Downstate Medical Center
- University of Calgary
- University of Pittsburgh
- University of California, Los Angeles
- Univ of Medical and Dental of NJ
- Univ of North Carolina, Chapel Hill
- Yale University
- Univ of Texas SW Medical Center
- Weill Cornell Medical College
- Dartmouth University
- Nathan Klein Institute
- Burrell Behavioral Health

## **Research Foundation for Mental Hygiene (RFMH)**

PI: Jeffrey Lieberman, MD

- Columbia University
- University of Maryland, Baltimore
- Westat, Inc.
- Dartmouth University
- University of California, Los Angeles
- Duke University
- Univ of North Carolina, Chapel Hill
- University of California, Davis
- Beth Israel Deaconess Medical Ctr
- Sheppard Pratt



# Similarities

- Multi-modal, evidenced-based treatment
- Integrated treatment teams
- Personalized care
- Emphasis on engagement and recovery
- Client/family members involved in decisions regarding treatment choices



# Differences

- Financing structure for interventions
- Specific components of services offered
  - Medication algorithm
  - Domains addressed
- Approaches to treatment decision making
- Aspects of Phase 3 practical clinical trial design



# Trial Designs

	<b>FIMR</b>	<b>RFMH</b>
<b>Sample Size</b>	400	330
<b>Ages</b>	16 – 40 years	15 – 35 years
<b>Control Group</b>	Treatment as Usual (TAU)	TAU plus Case Management
<b>Randomization</b>	Site (20 – 30)	Individual
<b>Financing</b>	Reimbursement through public or private insurance	Reimbursement through public or private insurance; for noninsured, funding from state mental health authorities (NY, MD)



# Stakeholders' Meeting

July 16-17, 2009

- “The aim is to incorporate feedback from key stakeholders outside of the investigative team to achieve broad-based consensus regarding the public health importance of the intervention and the scientific merit of the study design.”
  - Consumers and family members
  - Clinicians and mental health service administrators
  - Federal Agencies
  - Scientific community



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# Data Harmonization Meeting

## October 28, 2009

- Common measurement strategies for:
  - Duration of untreated psychosis, treatment history
  - Premorbid functioning, diagnosis, symptoms
  - Continuation and dropout status
  - Side effects and adverse events
  - Remission, relapse, re-hospitalization
  - Functional outcomes, quality of life



# Next Steps

- DHHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) review of financing mechanisms for early psychosis treatment, Spring, 2010
- Phase 2 to start Spring 2010
- Phase 3 to start Winter 2011

