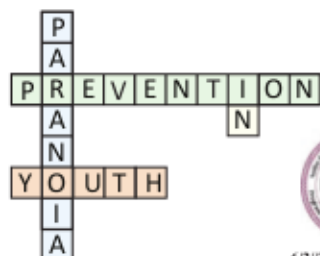


Research Study



6/2/2016 - 6/1/2017
GCO 15-0871

Cognitive Behavioral Therapy

for the Prevention of Paranoia
in Youth at Risk

Information for Referring Clinicians

Please contact:

Dr. Yulia Landa - yulia.landa@mssm.edu

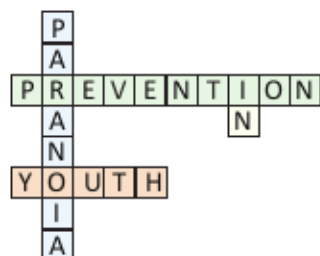
or Rachel Jespersen - 212-659-5606

rachel.jespersen@mssm.edu

with referrals or any further questions.

This study has been approved by Icahn School of Medicine at Mount Sinai Institutional Review Board.
IRB protocol # 15-0871

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Principal Investigator:
Yulia Landa, PsyD, MS
Study Coordinator:
Rachel Jespersen, LMSW

Location of the Study:
Icahn School of Medicine at Mount Sinai, Department of Psychiatry,
Aron Hall, 50 East 98th Street, Suite 1B, New York, NY 10029

Study Aim:
To prevent or delay the transition to psychosis and to decrease the severity of symptoms and functional impairment in youth who are at high risk of developing paranoid delusions by providing a specialized Cognitive-Behavioral Therapy (CBT) program.

Research Overview:
30 youth between the ages of 12 and 25 will be recruited. 6 subjects will participate in the feasibility trial. 24 subjects will participate in the pilot randomized controlled trial and allocated to CBT or standard care.

Specialized CBT Program:
Aims to reduce paranoia-biased information-processing and social avoidance, increase insight and reality testing capacity, and sharpen logical reasoning skills in order to prevent the formation of stressful paranoid thoughts or beliefs.

Duration 15 weeks and includes weekly:
- 1 hour group and 45 min individual therapy for youth
- 1 hour support group for family members (to learn how to help youth practice CBT skills).

Assessments:
At baseline, post-CBT and 4-month follow-ups for 2 years.

Inclusion Criteria:
Ages 12-25, meet criteria for an "At Risk Mental State", exhibit suspiciousness, identify one family member who has > 4 hrs/week contact with the youth and is willing to participate; and are able to sign informed consent.

Exclusion Criteria:
Moderate to severe learning disability; organic impairment; substance dependence; schizophrenia; schizoaffective disorder.

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What is "At Risk Mental State"?

Youth who report **at least 5 of the experiences** described below are likely to meet our study inclusion criteria:

- ✓ At times confused if something they experienced was real or imaginary.
- ✓ Holds beliefs that other people would find unusual or bizarre.
- ✓ Thinks that some people drop hints or say things with a double meaning.
- ✓ Often feels that other people are watching them or talking about them.
- ✓ Concerned that people in their life are not loyal or trustworthy.
- ✓ Often picks up hidden threats or put-downs from what people say/do.
- ✓ Feels that others don't like them and may wish to hurt them.
- ✓ Sometimes feels that things he/she sees on the TV or read in the newspaper have a special meaning.
- ✓ At times worries that something may be wrong with their mind.
- ✓ At times feels that they are not in control of their own ideas/thoughts.
- ✓ Experiences with the supernatural, astrology, seeing the future.
- ✓ Believes in telepathy, psychic forces, or fortune-telling.

We would appreciate referrals:

Please give eligible youth and their family members information about our study and our study flyer, so that they can call us. Alternatively we would appreciate if you could ask them for permission that one of our study investigators contact them to tell about the study.

In our experience, the best way to tell the patients about the study has included the following points:

- ✓ This is a research study examining the effectiveness of CBT (a therapy that focuses on helping people feel better by learning new coping strategies and effective ways of thinking) to prevent the unnecessary suspicious thoughts and fears.
- ✓ CBT is free of charge.
- ✓ Family members will participate in a support group where they will learn how to help youth practice CBT skills.
- ✓ Youth will continue to receive standard care. Their current treatment will not be affected.
- ✓ All information will be kept strictly confidential.
- ✓ Participants will receive up to \$500 total compensation per family for completing assessment interviews.

This research is sponsored by: Sidney R. Baer Jr. Foundation

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