Young Adults With Violent Behavior During Early Psychosis: An Open Pilot Trial

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NCT05756855

PROTOCOL: Young Adults and Violent Behavior During Early Psychosis (NCT05756855)
NYSPI Protocol #8451 / Columbia University IRB Protocol AAAU8528

1. Protocol Synopsis

Study Type	Prospective, interventional, open pilot trial of a manualized cognitive behavioral therapy (CBT)-based behavioral intervention
Setting	OnTrackNY early intervention services (EIS) clinics in New York State
Study Population	Participating EIS clinicians and adult EIS participants receiving coordinated specialty care from participating clinicians
Target Enrollment	Up to 16 EIS participants
Intervention	Twelve individual CBT sessions, approximately 45 minutes each, delivered by the participant's own EIS clinician
Primary Focus	Feasibility and acceptability of the adapted intervention, using mixed-methods assessment to guide iterative refinement
Primary Endpoint	End of the 12-week treatment period, with weekly follow-up assessments

2. Background and Rationale

Young adults with early psychosis have elevated rates of violence compared with the general population, although the absolute risk of violence among people with serious mental illness is small. Risk factors identified in this population include hostile affect, criminal justice involvement, involuntary treatment, lower educational attainment, and substance use. Cannabis may be particularly relevant through associations with paranoia and other positive symptoms.

Early psychosis is a critical period for intervention. Early intervention services improve quality of life, participation in work and school, treatment engagement, hospitalization outcomes, and symptoms. CBT is an important component of treatment for early psychosis and teaches people to identify relationships among thoughts, emotions, and behaviors and to develop skills they can use independently.

CBT-based approaches have shown promise for reducing violent and aggressive behavior. The PICASSO model is a CBT intervention targeting violence, anger, and psychosis. Prior randomized research in adults with schizophrenia-spectrum disorders found less physical aggression among participants receiving PICASSO than among participants receiving a control intervention. However, CBT interventions specifically targeting violence risk in young adults with early psychosis have not been adequately tested. The present study adapts this approach for an EIS setting and evaluates its feasibility and acceptability in an open pilot trial.

3. Study Objectives

Primary objective: To adapt a manualized behavioral intervention using CBT for the EIS setting in an open pilot trial through an iterative process utilizing mixed-methods assessment.

4. Study Design

This is an open pilot trial conducted within the OnTrackNY network. All research participants will continue to receive standard clinical treatment; treatment will not be held or withheld as a result of study participation. The intervention will be refined iteratively using feedback from participating clinicians and EIS participants.

Participating clinicians will receive refresher training in CBT and training in the adapted PICASSO intervention. Weekly supervision will be available during intervention delivery. With appropriate consent, a subset of therapy sessions may be audio-recorded for fidelity.

5. Study Population and Eligibility

5.1 EIS Clinicians

Inclusion criteria:

- Age 18 to 75 years.
- Licensed mental health clinician employed in a clinician role at an OnTrackNY-affiliated clinic.
- Willing to participate in the study, including audio-recorded interviews.

Exclusion criteria:

- Unable to provide informed consent.
- Not fluent in speaking, reading, and writing English.

5.2 EIS Participants

Participants must be receiving coordinated specialty care through OnTrackNY or an affiliated clinic and meet the study-specific criteria below.

Inclusion criteria:

- Adult participant receiving coordinated specialty care from a participating clinician at OnTrackNY or an affiliated clinic.
- Within two years of onset of psychotic symptoms.
- Identified by the EIS clinician as appropriate for the study, including being psychiatrically stable enough to participate.

- Willing to participate in the study, including audio-recorded research interviews.

Exclusion criteria:

- Unable to provide informed consent.
- Not fluent in speaking, reading, and writing English.
- History of antisocial behaviors, assessed using the CATIE questionnaire items addressing major conduct problems before age 15.

6. Recruitment and Informed Consent

Participating clinicians will be recruited first from OnTrackNY sites. OnTrackNY personnel may email staff a study description, and trained research personnel may describe the study during clinic team meetings. Participation by clinicians is voluntary.

After consent, participating clinicians will identify patients from their current panels who may be appropriate for the study. Clinicians will document a patient's interest in learning more, after which trained research personnel will screen the patient by telephone or in person. Written informed consent will be obtained before study participation. Consent may be completed in person or electronically through REDCap during a HIPAA-compliant videoconference.

7. Intervention

The behavioral intervention consists of 12 individual CBT sessions, approximately 45 minutes each, delivered by the EIS participant's own clinician. Sessions occur within the participant's EIS clinic and may be rescheduled in accordance with clinic procedures. The assessment schedule may be adjusted so study assessment weeks remain aligned with intervention weeks.

The intervention includes five modules:

- Engagement: motivational strategies and collaborative engagement in treatment.
- Assessment: individualized identification of problems, including psychosis, functioning, substance use, anger, and aggression.
- Formulation: collaborative development of an understandable formulation linking symptoms, beliefs, emotions, and behavior and identifying treatment goals.
- Intervention: CBT strategies selected according to the formulation and participant goals, including work on psychosis, anger, substance use, mood, medication adherence, or related targets.
- Relapse prevention: consolidation of progress and development of strategies for ongoing management of aggression, anger, and violence risk.

8. Study Assessments and Outcome Measures

The primary outcomes are feasibility and acceptability. Mixed-methods data will be collected throughout the 12-week intervention to guide further adaptation.

8.1 Feasibility and Acceptability

- Brief cognitive interview with EIS participants following each intervention session.
- Recruitment, retention, attendance, and homework completion tracked as feasibility indicators.
- EIS clinicians complete the Feasibility of Intervention Measure (FIM) and Acceptability of Intervention Measure (AIM) weekly.
- EIS clinicians participate in semi-structured interviews at Weeks 4, 8, and 12 focused on appropriateness, strengths and weaknesses, adaptations, and recommendations for improvement.

8.2 Secondary/Exploratory Measures

- Violence: Columbia Initial Screen for Violence (CIS-V).
- Impulsivity: Barratt Impulsiveness Scale (BIS-11) and short UPPS-P.
- Substance use: AUDIT-C, CUDIT-R, and DUDIT.
- Psychotic symptoms: COMPASS-10.
- Medication adherence: Modified Brief Adherence Rating Score (BARS).
- Hostility: Buss-Durkee Hostility Inventory (BDHI).
- Trauma: Adverse Childhood Experience (ACE) and Life Events Checklist for DSM-5 (LEC-5).

Baseline assessment is expected to take approximately 45 minutes. Enhanced assessments at Weeks 4, 8, and 12 are expected to take approximately 30 minutes. Weekly follow-up assessments are expected to take approximately 5 minutes for clinicians and 5-10 minutes for EIS participants.

9. Statistical Procedures

This study will produce a refined manualized CBT intervention to reduce violent behavior for patients receiving care in EIS settings. Although this study is not powered to test a formal hypothesis for reduction in violent behavior or target mechanism, information about the target and each of the identified potentiators will be presented descriptively, with analysis of inter- and intra-individual patterns of behavior over the time of the intervention. These results will be used to estimate effect size, to determine sample size for a future powered study.

10. Risks and Potential Benefits

10.1 Risks

For EIS clinicians, risks are minimal. Participation involves activities similar to usual clinical duties. Clinicians may decline or stop participation at any time, and participation will not affect employment.

For EIS participants, anticipated risks include:

- Emotional distress from discussion of sensitive information.
- Disclosure of violent or suicidal thoughts or behaviors.
- Breach of confidentiality or loss of privacy.

10.2 Potential Benefits

The study is designed to refine a CBT-based behavioral intervention for young adults with early psychosis. Participants may or may not experience direct clinical benefit. The study may provide information useful for improving future interventions to reduce violence risk in early psychosis.

11. Safety Monitoring and Early Discontinuation

All EIS participants will continue receiving care through their OnTrackNY clinical teams, which retain primary clinical responsibility and use their usual safety and suicide-risk management procedures. If a participant raises an acute safety concern to research staff, the concern will be escalated to the principal investigator and the participant's clinical team for appropriate clinical evaluation and management.

EIS clinicians must remain employed with OnTrackNY or an affiliated clinic for continued study participation. EIS participants must remain in treatment with OnTrackNY or an affiliated clinic. Participants who leave treatment will be discontinued from the study. Participants who are hospitalized or engage in violence may continue if they return to OnTrackNY treatment. When possible, Week 12 follow-up assessments will be completed at the time of early discontinuation.

A Data and Safety Monitoring Board will meet prior to trial initiation. Safety events and serious adverse events will be handled and reported according to the approved protocol and applicable institutional requirements.

12. Data Collection

Study assessments may be completed in person or remotely. Study data are entered into REDCap; paper measures may be used temporarily when needed and then entered into the electronic study database. Audio-recorded interviews are transcribed for qualitative analysis. Reports of study findings will use aggregate or de-identified information.

13. Funding and Registration

This investigator-initiated study is supported by the National Institute of Mental Health under K23MH126312. The study is registered at ClinicalTrials.gov as NCT05756855.