Center for Social Innovation
OnTrack>An Online Role-Playing Game
Research Protocol

PROJECT INFORMATION

Project Title: *OnTrack>An Online Role-Playing Game: Phase II*
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Funding Agency: National Institute of Mental Health
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PURPOSE AND OBJECTIVES

Schizophrenia is a potentially devastating illness that typically affects adolescents and young adults between 15 and 30. The disorder is marked by *psychotic symptoms*, such as delusions and hallucinations; *negative symptoms*, such as withdrawal and lack of motivation; and *cognitive symptoms*, such as poor attention and organization. Until recently, the course has been characterized by recurrent exacerbations and remissions that result in a chronic state of residual symptoms and functional impairment.[i,ii] The annual costs of schizophrenia in the United States have been estimated to be approximately $60 billion, including direct medical costs, non-health care costs, and lost productivity.[iii] These costs result from individuals becoming ill early in life, and then subsequently experiencing high rates of unemployment and psychiatric and medical comorbidities.

A growing body of evidence suggests that programs designed to treat people experiencing early psychosis can reduce hospitalization, decrease psychiatric symptoms, improve quality of life, and result in better social and occupational functioning. The availability of antipsychotic medications and recovery-oriented psychosocial treatments, as well as accounts from individuals diagnosed with schizophrenia who have recovered, have begun to change expectations. Research from the last two decades has inspired optimism for development of a comprehensive strategy that has the potential to minimize, if not prevent, the cumulative morbidity of this once-debilitating illness.[i] In 2008, NIMH launched the Recovery After Initial Schizophrenia Episode (RAISE) Project.[iv] The project resulted in coordinated specialty care (CSC) models, including OnTrackNY, an early intervention program designed to identify and treat young people experiencing first episode psychosis (FEP). Engaging young people in relationships with providers, family, and friends can play a critical role in treatment and recovery.

Despite the increased focus on CSC, a need remains to develop, test, and disseminate accessible tools for young people to understand their experiences with psychosis, seek support, and engage in care. Engagement in care remains critical for young adults who have experienced first episode psychosis, yet few tools have been developed to support such engagement. Research has emerged in recent years to support the role of online gaming as a tool for therapeutic engagement, behavioral rehearsal of real-world situations, and working through difficult decisions in a low risk environment.[v,vi,vii,viii,ix] An opportunity exists to apply gaming theory and technology to support young people who have experienced FEP.

In response to this opportunity, the Center for Social Innovation LLC (C4) partnered with Dr. Lisa Dixon, principal investigator of the RAISE-IES study and director of OnTrackNY, to

develop and test a prototype version of *OnTrack>An Online Role-Playing Game (OnTrack>The Game* or *OTG)*, an online role-playing game designed for youth and young adults experiencing FEP. The Phase I SBIR (NIMH #1R43 MH105013-01) brought together C4's experience developing innovative learning technologies with the subject matter expertise of Dr. Dixon and her team. Phase I showed positive changes in quantitative measures of hope and recovery, as well as an enthusiastic response to the prototype as evidenced by qualitative interviews (see *Significance* section in full proposal). These findings suggest the need for and feasibility of conducting a Phase II study.

The proposed mixed-methods Phase II study will use standardized measures and semi-structured qualitative interviews to achieve the following aims:

1. **Product aim**: To refine, expand, and finalize *OnTrack>The Game.* Building on the Phase I prototype, we will improve functionality, expand the play spaces and levels, add interaction with non-player characters, include more resources on FEP, and expand the library of videos on hope and recovery.
2. **Primary research aim**: To evaluate the effectiveness of a role-playing game (*OTG*) in increasing empowerment, decreasing stigma concerns, and improving treatment engagement.

   Hypothesis 1: Compared to control condition (Recovery Videos, or *RV),* participants in *OTG* will report significantly increased empowerment at 2 months post-intervention compared to baseline.
   Hypothesis 2: Compared to the control condition (*RV*), participants randomized to the *OTG* condition will report significantly increased empowerment, (Herth Hope Index, Recovery Attitude Questionnaire, Roger's Empowerment Scale), decreased stigma concerns (Questionnaire on Anticipated Stigma, Rüsch Stigma Stress), and greater treatment engagement (Signh O'Brien Level of Engagement Scale, engagement with CSC program) at the 5-month follow-up compared to baseline.
3. **Secondary research aim:** To determine if changes in empowerment and stigma concerns mediate the effect of *OnTrack>The Game* on treatment engagement.

   Hypothesis 3: Increases in hope, attitudes toward treatment, and self-efficacy and decreases in stigma concerns at post-treatment will partially mediate the improvement in treatment engagement at follow-up.

METHODS

Research Design

To evaluate the impact of the game in this Phase II study, we will conduct a randomized controlled trial (RCT) enrolling 200 clients randomized to *OTG* or a control condition of *RV*s in a 1:1 ratio. We will recruit these participants from OnTrackNY's Early Intervention for Psychosis (EIP) clinical centers after screening for eligibility. After consent and initial interview (baseline), participants will be randomly assigned to either *OTG* or *RV*. Following an intent-to-treat framework, we will then assess each client participant at 2 additional time points regardless of participation in their assigned condition: post-intervention at 2 months and follow-up at 5 months after baseline. Ten clinicians working with these clients will also be recruited for semi-structured key informant qualitative interviews. Our rationale for selecting a randomized controlled design stems from our Phase I findings, which suggest that the game may be effective in addressing young people's hopefulness, stigma, and understanding around first episode psychosis. An RCT design will allow us to examine how specific aspects

of the game impact outcomes in these areas, as compared to more static, passive online resource.

Subjects, Sampling, and Recruitment

Subjects

OnTrackNY is New York State's coordinated specialty care (CSC) program. Funded by state dollars, a SAMHSA Healthy Transitions Grant, and Mental Health Block Grant funds, the state currently supports 13 teams throughout the state. Eight additional programs are expected to come on line within the next 6 months. The program serves young adults ages 16 to 30.

At the time of funding, we expect 14 CSC sites to be located in downstate New York. Although sites will have different numbers of clients (20–40), approximately 450 clients will be participating in the program at that time. Based on the 2-year program, approximately 225 new clients will start the program during the year of recruitment. Based on our previous experience, we believe we will be able to recruit 33% of the eligible clients. If for some reason, we fall short of our recruitment goals, we will use the other OnTrackNY sites until we meet our goal. We anticipate no challenges in recruiting clinicians (n=10).

Sampling

Client Inclusion Criteria: Client study participants will be individuals currently enrolled in OnTrackNY who wish to enroll and who meet these inclusion criteria: (1) between the age of 16 and 30; (2) receiving services at one of the host sites; (3) able to give fully-informed consent; (4) willing and available to take part in the intervention conditions, 3 in-person quantitative assessments, and possibly a semi-structured qualitative interview; (5) engaged in the EIP program for less than a year; (6) access to the internet with a personal computer or tablet (if this is a barrier, sites can provide access); (7) access to email; and (8) are English speaking. *Exclusion criteria*: Not meeting inclusion criteria. RAs will screen each interested individual and schedule a consent appointment if interested and eligible.

Clinician Inclusion Criteria: Clinician criteria include mental health professionals who (1) are providing care in a host site and working with a client participating in the study, (2) are willing to complete study requirements and provide signed informed consent, and (3) are English speaking.

Review of participant enrollment and compliance with inclusion/exclusion criteria will occur monthly during recruitment to ensure that a sufficient number of participants are being enrolled and that they meet eligibility criteria and the targeted race and ethnic diversity reflected in the enrollment tables of the proposal (see Targeted Enrollment tables in proposal).

Recruitment

We will recruit client participants via flyers and announcements at the sites, clinician referrals, and review of clinic rosters (after obtaining a partial HIPAA waiver). After explaining the study, RAs will screen interested clients and schedule a consent appointment if indicated. All RAs are trained in informed consent procedures and will explain participation risks and benefits, confidentiality risks and protections, the voluntary nature of participation, that participating or not will not affect one's services, and that the participant may withdraw at any time with no penalties. RAs are trained and supervised regarding informed consent with people with psychosis who may have cognitive, attention, and processing difficulties. RAs will administer a brief questionnaire to verify that the person is competent to provide consent and demonstrates comprehension of the consent document. If the client does not answer all questions correctly,

the RA clarifies points of confusion then re-administers the questionnaire. Clients again failing to answer questions correctly will not be consented into the study. Purposive sampling will be used to recruit clinicians for semi-structured interviews.

We have extensive experience maintaining participant engagement and contact during intervention studies. Once enrolled, we ask participants to complete a contact information form that we have found effective in other studies for maintaining communication and participant retention. It requests multiple ways to reach the person (phone, email, letter) and people of the participant's choosing we may contact if the primary methods of contact are unsuccessful, preferences around communication details (such as whether we may leave a voice message on a given phone number and with what specificity), and signed confirmation that we have permission to use the information for study communications. Study staff then make reminder calls/texts prior to each study activity (assessment, group meeting, individual consultation) throughout the study. These contacts serve to remind participants of the meetings, to answer questions, help avoid or resolve attendance obstacles, and maintain a high level of positive mutual engagement. Study staff also engages in active outreach if/when participants miss a study activity. Based on our previous work and the timeframe of the follow-up assessments, we estimate 10% attrition at 2 months and 20% attrition at 5 months.

Study Conditions

Clinicians will be oriented to both study conditions (the game and the website) via a brief (15-minute) presentation that will also be available as an online video. For all study participants, we will request clinicians make 3 simple inquiries with respect to viewing the videos/information on the website or playing the game: Have you had a chance to look at the website/play the game in the last week? Was it helpful? Is there anything you want to talk about? Potential follow-up questions will also be discussed with clinicians. From this pool of clinicians, we will recruit 10 to participate in semi-structured interviews on their experiences in working with clients participating in each study condition (e.g., observations of changes in attitudes toward treatment, self-efficacy, a sense of hope, treatment engagement, and stigma).

Following informed consent, the RA will open the envelope indicating to which intervention the participating client was randomized. For people in the *OTG* condition, the RA will review an outline of the game, provide directions on how the game works, and reiterate the expectation that the participant will finish the game in the following 2 months, if not sooner. We expect that spending 1 hour a week playing the game will be sufficient to complete all levels of the game. For participating clients in the *RV* condition, they will be reminded that they are expected to view the recovery videos and download the information materials from the website. We anticipate that the materials could be viewed in approximately 4 hours. The RA will remind the participant that they will receive an email with a link to either the game or the website, depending on their study condition. All participants will be provided with an email address and telephone number. If a participating client does not open the email with the link for 2 weeks, another email will be sent.

Intervention Description (OTG)

The intervention condition will consist of 2 components: (1) provision of the game to the participating clients via an email link, and (2) brief interactions with their mental health provider with respect to reactions they may have when playing the game. Components of the game are described in the *Innovation* section of the proposal. The participant will be reminded via email once a week to play the game/visit the website for a period of 2 months. After that time,

reminders to play the game/visit website will no longer be sent, but the participant may continue to play if they wish.

Control Condition (RV)
The control condition will consist of access to a website that will contain the recovery videos and the static information that is contained in the game. In the control condition, mental health providers will also ask about possible reactions to viewing the recovery videos and information on the website. At the end of the study (after the follow-up assessment), the *RV* participants will be provided access to the game. The table below shows how the conditions align.

Component	***OnTrack>The Game (OTG)***	***Recovery Videos* Website (*RV*)**
1. Testimonials of Hope and Recovery	Movie theater zone with 20 brief (3–5 minute) video interviews with young adults who have experienced psychosis.	Online library of the 20 video interviews from *OTG*
2. Information on First Episode Psychosis	A "virtual computer" in player's apartment contains information about psychosis, treatment options, medication management, and wellness strategies.	Repository of handouts covers the same information as the game's "virtual computer"
3. Online role-playing to support behavioral rehearsal of life events; cognitive rehearsal of problem solving skills; and low-risk interactions with friends, family, co-workers, and providers	Players move through levels of the game, complete quests, and interact with non-player characters. Real-life situations, including bad thoughts and random events, allow players to rehearse behavioral and cognitive skills to respond. Interactions with non-player characters simulate human interaction in the real world.	NA

Incentives

Client Incentives
Clients will have the opportunity to receive $100 for participating in the Quantitative Assessments (n=200; $30 for baseline assessment; $30 for post intervention assessment; $40 for follow-up) and an additional $25 if they are asked and freely decide to participate in semi-structured qualitative interviews (n=20). The total possible compensation is $125 for those participants who are chosen for the interviews and complete all three quantitative surveys.

Clinician Incentives:
Clinicians will receive $50 for their participation in Semi-Structured interviews (n=10).

Data Collection
We will use a mixed-methods approach of standardized measures and semi-structured qualitative interviews to address the following aims:

> **Product aim**: To refine, expand, and finalize *OnTrack>The Game.* Building on the Phase I prototype, we will improve functionality, expand the play spaces and levels, add interaction with non-player characters, include more resources on FEP, and expand the library of videos on hope and recovery.
>
> **Primary research aim**: To evaluate the effectiveness of a role-playing game (*OTG*) in increasing empowerment, decreasing stigma concerns, and improving treatment engagement.

Secondary research aim: To determine if changes in empowerment and stigma concerns mediate the effect of *OnTrack>The Game* on treatment engagement.

This section describes data collection procedures designed to answer the primary and secondary research aims.

Qualitative: Qualitative data collection will include semi-structured key informant interviews with a small subset of participating clients and clinicians after clients have completed the intervention.

Client interviews: A subset of 10 clients from each study condition (n=20) will be asked to participate in semi-structured interviews after using *OTG* or *RV*. Questions will explore their experiences in using the product (navigation and access, preferences, facilitators and barriers to use); attitudes toward treatment and working with their clinician; and their feelings of self-efficacy, recovery, hope for the future, and stigma. Clients will receive $25 for participating in these interviews.

Clinician interviews: Ten clinicians, working with clients from both study conditions, will also be asked to participate in semi-structured interviews to explore their experiences in working with clients from each condition and changes in attitudes they may have observed, barriers and facilitators to use of each product, and feedback on the product components. Clinicians will receive $50 for participating in these interviews.

We feel that the number of interviews described will be sufficient to reach data saturation, but we will add interviews if needed.

Quantitative: Baseline, post, and follow-up surveys will be completed with each study participant via in-person interviews using direct data entry into a secure online database built with Qualtrics software. Baseline assessment will occur at the time informed consent is obtained if possible, and at this time we will ask participants for demographic data including age, gender, race and ethnicity, education level, relationship/marital status, work, and school participation. Data on treatment engagement will be extracted from clinic charts.

The following table presents domains, measures, and time-points for administering them.

Quantitative Measures and Frequency of Assessments by Specific Aim				
Domain	Measure	Administered at study time-point		
		BL	Post	Follow-up
Aims 2 and 3				
Stigma Concerns	Rüsch Stigma Stress	x	x	x
	Questionnaire on Anticipated Discrimination			
Empowerment	Recovery Attitude Questionnaire (RAQ)	x	x	x
	Roger's Empowerment Scale Total			
	Herth Hope Index (HHI)			
Treatment Engagement	Singh O'Brien Level of Engagement Scale (SOLES)	x	x	x

	Number of unduplicated visits during the follow-up period is above engagement threshold			x
Description of Sample and Potential Moderators and Mediators				
Participant Demographics	Demographic Form/Chart Review	x		
Experience with Game Functionality and Design	EGameFlow		x	x
Use of Game/Website	Springroll Learning Module/Google Analytics		x	x

Data Analysis

All data will first be screened for errors via frequency and contingency tables and univariate and bivariate plots. These will also allow us to check for missing data and that variable distributions are compatible with the statistical models we will use.

Triangulation increases confidence in the validity of a finding if it converges across disparate sources of information. Qualitative data will be triangulated by sources (comparing client and clinician interview data). Further, the research team will also actively work to integrate quantitative and qualitative datasets, comparing results during and after analysis, to allow for ongoing interpretation.

We will use a mixed-effects, 2-level model (SAS Proc Mixed, GLIMIX) to test primary hypotheses with a random class effect to account for intra-team correlation (ICC). The longitudinal assessments (baseline (t=1), post-treatment (t=2), and 6-month follow-up (t=3) will be nested within participants and participants nested within teams. Adjustment for baseline response will reduce residual variation at t=2 and t=3 resulting in greater power. Correlation in the response at t=2 and t=3 (conditional on response at t=1) will be modeled by allowing the corresponding error terms to be correlated rather than using a random individual effect. That is, we will use a hybrid model with both a random class effect and correlated error terms (conditional on baseline value and the class effect).

Quantitative Analysis

Aim 2: A Generalized Linear Mixed Model will be used with the outcome measures listed above as the dependent variables and treatment group (*OTG* vs. *RV*) as the independent variable of interest. Baseline outcome measures and any covariates determined from preliminary analyses will also be included in the model. Post hoc analyses will include assessment of treatment group differences in the outcome measures at post-intervention and 3-month follow-up. Engagement will be binary variable; therefore a log link will be employed. The test of hypothesis 1 and 2 will operationally be the test of whether the coefficient of the *OTG/RV* condition term is significantly greater than zero (2-sided test) for each contrast.

Aim 3: The IV will be group assignment at baseline, the outcome will be treatment participation at the 3-month follow-up time point, the mediators (see Aim 2) will be measured at post-intervention, controlling for baseline. The PROCESS macro for SAS will be used to generate 95% bias corrected confidence intervals for the relative indirect effects as well as all

other parameters. PROCESS can also be used to assess multiple mediators as well as moderated mediation if desired.

Exploratory Analyses: Google Analytics (time spent playing game/viewing website) and EGameFlow data (experience with game functionality and design) will be used to assess any possible moderator effects on the outcome measures. In addition, demographic variables will be explored as moderators.

Qualitative Data Analysis

The further examination of Aims 2 and 3 via semi-structured interviews with clients and clinicians will include thematic analyses of the interviews to provide context and aid in interpretation of quantitative data. Interviews will be recorded and transcribed. We will begin with an a priori coding system for theme identification, developing a codebook with specific codes based on protocol questions but allowing for open coding as themes emerge during analysis. Data will be coded individually by multiple team members. After initial data analysis using NVivo qualitative data analysis software, the research team will discuss and review the emerging codes, establish intercoder agreement, refine constructs and coding categories, identify core themes and generate hypotheses about patterns in the data, and explore additional aspects of the data.

PROTECTION OF SUBJECTS AND USE OF INFORMED CONSENT

The research described in the Phase II proposal of *OnTrack>An Online Role-Playing Game (OnTrack>The Game* or *OTG)* involves data collected from clients who have been referred to OnTrackNY sites. It also includes qualitative interviews with clinicians. The Center for Social Innovation (C4) and the Research Foundation for Mental Hygiene, Inc. (RFMH) at the New York State Psychiatric Institute (NYSPI) and Columbia University will respect the confidentiality of individuals participating in the study and will obtain Institutional Review Board (IRB) approval through NEIRB and any other local IRBs for all research activities.

Throughout this Phase II study, Jeff Olivet, Co-PI; Dr. Lisa Dixon, Co-PI; Dr. Deborah Medoff, senior quantitative researcher; and Dr. Kathleen Ferreira, senior qualitative researcher, will be responsible for data and safety monitoring with the study team. The team will review rates of enrollment and retention on a regular basis to ensure that a sufficient number of participants are being enrolled and that they meet eligibility criteria and the targeted race and ethnic diversity reflected in the enrollment tables of the proposal. In the event of an unforeseen Adverse Event, per NIMH protocol, the Principal Investigator will notify the NIMH project officer in writing within 24 hours. Risks will be continuously monitored, and appropriate measures will be implemented in the event of an unanticipated challenge.

Informed Consent

Written informed consent will be obtained from each subject at entry into the study. The consent process will be conducted by research staff who have completed human subjects certifications. Informed consent is obtained by the process described below.

Clinicians will be oriented to the study with a brief presentation and online video. After explaining the study, RAs will screen each interested individual and schedule a consent appointment if interested and eligible. All RAs are trained and experienced in informed consent procedures and will explain participation risks and benefits, confidentiality risks and protections, the voluntary nature of participation, that participating or not will not affect one's

services, and that the participant is free to withdraw at any time with no penalties. RAs are additionally trained and supervised regarding informed consent with people with psychosis, who may have cognitive, attention, and/or processing difficulties. RAs will administer a brief questionnaire to verify that the person is competent to provide consent and demonstrates comprehension of the consent document. If the person does not answer all questions correctly, the RA clarifies points of confusion and then re-administers the questionnaire. Individuals again failing to answer the questions correctly will not be consented into the study. Individuals will be given ample opportunity to consider participation in the study and to ask questions regarding risks and benefits.

Individuals aged 16 and 17 may be included in the study. With participants under the legal age for consent, RAs will obtain participants' assent, or affirmative agreement to participate, as well as permission from a parent or guardian. The parental informed consent form will include contact information for the research team; parents and potential youth participants will be encouraged to contact the team if they should have any questions or concerns prior to, during, or following participation. We will work with the IRB to determine how parental permission and minor participant assent will be documented and ensure adequate provisions for protecting minor participants.

Confidentiality of Data

In order to ensure confidentiality, the research team will maintain a password-protected database to record contact information, dates, and other details associated with all phases of the study, including all recruitment activities, completion and submission of consent forms and data instruments, and scheduling of interviews. All electronic data collected throughout the study will be stored in password-protected databases or files. Each participant will be assigned a unique identification number, and a participant identification sheet will match participant names to their unique identifiers. The research team will keep a link file that will hold a crosswalk between the names and ID numbers of participants in a separate password protected file. Research data will only be identified by participant ID. Only IRB-approved research team members will have access to databases and to participant data. Paper forms, including site visit notes and consent forms, will be retained in a locked cabinet in the RFMH research office. Six months following the completion of the project, the record matching identifiers to participants will be destroyed.

Participant records will be securely stored for 3 years after completion of the study. The U.S. Department of Health and Human Services (HHS) protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for 3 years after completion of the research [per 45 CFR 46.115(b)]. At that time, our team will shred all paper copies of data and will delete all audio files and other data, such as transcripts, that are stored electronically.

All team members included within the research proposal will be required to undergo human subjects training which will be taken online through the National Institutes of Health (NIH) Office of Extramural Research (Protecting Human Research Participants) or the Collaborative Institutional Training Initiative (CITI). The course involves several components related to the protection of human subjects including, but not limited to, identifying and minimizing risks for research participants. Record of completion of the appropriate courses will be submitted to NIH and will supplement all IRB applications.

We will specify in the consent form and process that participation in this study is voluntary and the decision to participate in this study will not impact services received or staff employment.

There are no anticipated medical or psychological risk associated with either the intervention or control condition. However, all participants will be informed of the contact information for research team members who can be contacted in the occurrence of an adverse event.

STORAGE OF DATA

We maintain a password-protected database to record contact information, dates, and other details associated with all phases of the study, including all recruitment activities, completion and submission of consent forms and data instruments, and scheduling of interviews. Only IRB-approved research team members will have access to the data. All electronic data will be stored in password-protected databases or files. Paper forms, including site visit notes and consent forms, will be retained in a locked cabinet in the RFMH research office. An online database built with Qualtrics software will capture participants' demographic and clinical characteristics. Assessments will be completed via in-person interviews using direct data entry. Data will be exported from Qualtrics software into SAS 9.4 for analysis.

POTENTIAL RISKS

Clients may feel uncomfortable disclosing their mental health status to researchers. There is possible risk of coercion, mainly from the incentives that participants may be offered in the different research activities. The likelihood of this risk is low because compensation is commensurate with the amount of time required to complete this study. We will also specify in the consent form and consenting process that participation in this study is voluntary and the decision to participate in this study will not impact services received or staff employment. There is no greater risk associated with the comparison condition. The research team will clearly describe this risk and stress the importance of respecting the confidentiality of all participants. All study personnel will have successfully completed and/or updated their human subject's protection certification and will be trained on keeping data secure and participant information confidential. The benefits of this study far outweigh the minimal risks to study participants.

Safeguards are critical for clients, who will be sharing personal information about their mental health experiences. Safeguards will be put in place with participating programs in the event that a client experiences any form of distress, and immediate clinical support will be made available should it be necessary. This is the practice used in Phase I of the study and is always used when C4 staff work with individuals with mental health challenges. All participants will be reminded that participation is voluntary and that they can withdraw from the study at any point without reason or penalty. Once again, our primary concern is that we do no harm in working with clients during our study and that we take every precaution to avoid risk. This is why our team carefully considers inclusion/exclusion criteria and ensures that we are regularly attending to these criteria. The research team will work closely with the site liaisons, checking in regularly to ensure that it is appropriate for clients to continue to participate. Any concerns will be addressed at that time, and, as appropriate, the liaison and/or member of the research team will reach out to the client directly if deemed appropriate by their treatment team. If the team feels that clinically it is not in the best interest of the client to continue, we will discontinue the study with that individual.

This study will be stopped prior to its completion if (1) the intervention is associated with adverse effects that call into question the safety of the intervention (for this study, this would include a pattern of psychological destabilization of clients participating in the intervention), (2)

difficulty in study recruitment or retention will significantly impact the ability to answer study research questions, (3) any new information becomes available during the trial that necessitates stopping the trial, or (4) other situations occur that might warrant stopping the trial. The Co-PIs will include any of these challenges in the annual progress report to NIH/NIMH and will consult with the DSMB to assess the impact of significant data loss due to problems in recruitment, retention, or data collection.

Inclusion of Children

Because this randomized trial aims to test the effectiveness of an early intervention for first episode psychosis, the study population consists primarily of adolescents and young adults. To promote the generalizability of findings, this study will necessarily include clients under the age of 18. Nineteen percent of the individuals in treatment with OnTrackNY are under 18, and we expect to recruit approximately the same percentage for this study. Clients aged 16 and 17 may be enrolled in this study if they meet inclusion criteria and are willing to complete study requirements. For these participants, written informed assent and parental informed consent will be required to complete enrollment. A plan for adequate protection against risk for children is detailed further in the *Protection of Human Subjects* section of the final proposal. All clients under the age of 18 who will be eligible for this study have been referred to an OnTrackNY site, are able to provide informed assent, are English-speaking, are willing and able to take part in the intervention conditions and the three interviews, and have been engaged in the EIP program for less than a year.

All research procedures involving adolescents will be conducted at OnTrackNY, which provides routine early intervention care for each of the participants who will be recruited into this study. The program's facilities have a strong track record of successfully delivering care to adolescent participants under the age of 18 and are well equipped to accommodate the participants of this study. Moreover, our investigative team includes clinicians, researchers, and advocates who have years of experience either working directly with or developing interventions for adolescents in the field of behavioral health.

We have no hypotheses with respect to different outcomes for participants under 18.

BENEFITS

Potential benefits of this project, per current research, include reduced hospitalization, decreased psychiatric symptoms, improved quality of life, and better social and occupational functioning for youth and young adults with first episode psychosis who receive early intervention and treatment. The game provides an opportunity for these youth to experience a community in which they can learn about FEP and simulate and rehearse real-life situations in a safe, non-threatening environment.

Phase II research will allow C4, in collaboration with RFMH, to evaluate a refined version of *OnTrack>An Online Role-Playing Game* as a tool for engaging young people who have experienced first episode psychosis. The game is designed for young people with first episode psychosis to increase hope, improve attitudes toward treatment, increase self-efficacy, improve treatment engagement, and decrease stigma concerns. Engagement in care remains critical for young adults who have experienced first episode psychosis, yet few tools have been developed to support such engagement. The findings from the proposed research will speak to commercialization and broader dissemination and implementation. The intended outcomes greatly outweigh the risks associated with participating in this study.

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