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EXAMINING THE IMPACT OF FAMILY CONNECTORS

A study of 96 family members enrolled in Family Connectors (n=48) or a comparison condition (n=48).

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NYULMC Study Number:	**S12-01116**
Funding Sponsor:	P50MH113662
Study Locations & Roles	Washington University will be responsible for generating GUID IDs, that are needed for reporting to the National Data Archives. Wash U is not recruiting participants. NYU is responsible for all other study activity.

Initial version: 2021.09.15

Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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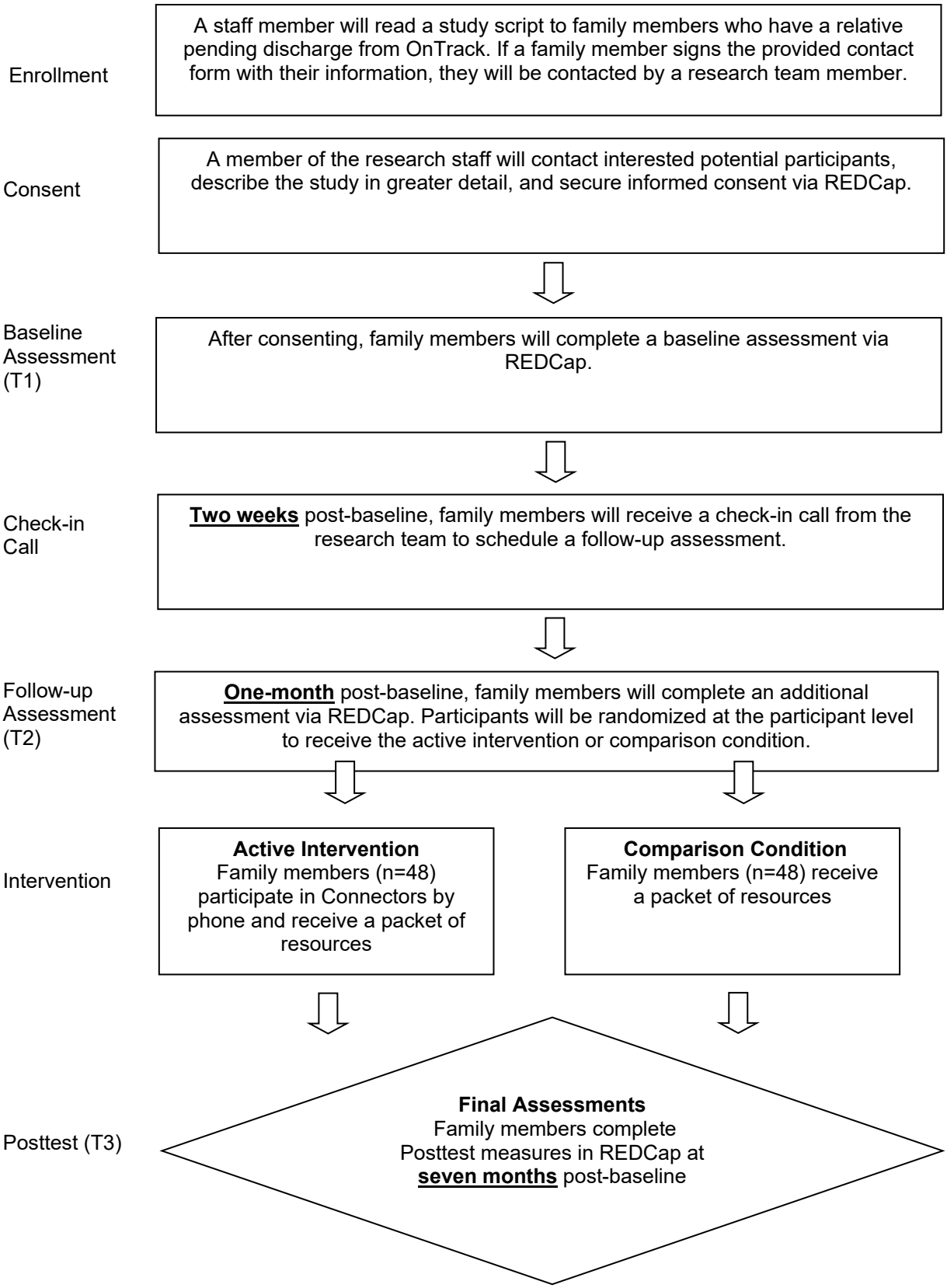
List of Abbreviations

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CRF	Case Report Form
DCC	Data Coordinating Center
FFR	Federal Financial Report
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIH	National Institutes of Health
NYC H+H	New York City Health + Hospitals
OHRP	Office for Human Research Protections
PI	Principal Investigator
QI	Quality Improvement
SAE	Serious Adverse Event/Serious Adverse Experience
US	United States

Protocol Summary

Title	Examining the Impact of Family Connectors
Short Title	Family Connectors
Brief Summary	This study will examine the impact of Family Connectors amongst 96 family members of adolescents/young adults with first episode psychosis who were discharged from OnTrack.
Objectives	The study objectives are to examine the association between involvement in Family Connectors, a manualized peer-to-peer support and education program for family members of adolescents or young adults with symptoms of first episode psychosis, and feelings of empowerment, self-efficacy and social support. A total of 96 family members will be enrolled in this study, and will be enrolled in either Family Connectors + a packet of community resources or the community resource alone. Outcomes consist of the family member's feelings of self-efficacy, connection to services and supports, caregiving strain, satisfaction, and perceptions of adolescent/young adult functional outcomes at school and work.
Methodology	RCT with data collection and baseline (T1), follow-up (one-month post-baseline, T2) and posttest (six months past T2xx).
Endpoint	The primary endpoint of the study is when data collection is completed for 96 participants.
Study Duration	Approximately 2 years.
Participant Duration	Approximately 9 months from enrollment to completion of posttest data.
Population	96 adults who are (1) English speaking, (2) 18 years of age or older, (3) a family member of an adolescent/young adult with first episode psychosis who was discharged from OnTrack.
Study Sites	The participating site is the NYU Langone School of Medicine and Washington University.
Number of participants	96 family members will be enrolled at NYU Langone School of Medicine
Statistical Analysis	Descriptive analyses will be conducted to calculate means and standard deviations for continuous data and numbers and percentages for dichotomous data. Bivariate and multivariate analyses will examine between and within group differences from baseline to posttest.

Schematic of Study Design



1 Key Roles

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2 Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

This study will observe the impact of the Family Connectors (FC) model on family members who participated in OnTrack, a treatment program for adolescents/young adults with symptoms of first episode psychosis. The Family Connectors Program is a manualized program that uses a time-limited parent-to parent (i.e. peer parent) support and education program delivered by phone to families of youth with serious mental health difficulties, assisting family members in becoming fully engaged with provider teams who coordinate and provide care. Family Connectors is delivered weekly by phone over the course of between three and six months.

This study has potential for significant impact in five ways: (1) it addresses a high-cost, serious, and significantly debilitating condition (FEP) with the goal of improving client outcomes; (2) it builds on a major national policy initiative and a state-wide priority in NYS; (3) it embeds an intervention tested in prior trials into Coordinated Specialty Care (CSC), enhanced with specialized engagement training offered by Co Lead Lindsey, a prominent mid-career researcher with expertise in engagement of low-income families of color; (4) the model is scalable, as it uses a low-cost, low-intensity enhancement strategy, improving potential for broad scaling in other states; and (5) it is nested within publicly-funded mental health (MH) sites that disproportionately serve low-income Y/YA.

Family Connectors provides emotional support (i.e., reducing parental stress and social isolation through providing emotional support), informational support (i.e., reducing parental stress and social isolation through providing emotional support), informational support (e.g., enhancing parental access to resources and information), positive attitudes (i.e., helping parents develop positive attitudes toward the importance of social support, perceived control, and expected benefits and actions), and caregiver strain.

We are seeking IRB approval to study the impact of Family Connectors upon family member outcomes (e.g., self-efficacy, caregiver strain, satisfaction with the program, social supports), and perceptions of their relative's (adolescents/young adults who participated in OnTrack) function and school outcomes.

2.2 Rationale

The study seeks to understand the impact of Family Connectors amongst a sample of family members who participated in OnTrack with their adolescent/young adult family member. Specifically, we seek to examine the impact of FC upon family member outcomes (e.g., self-efficacy, satisfaction with the program, engagement in supports), and functional outcomes and service use amongst adolescents/young adults.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

There are no physical, social or economic risks associated with participation. The primary risks associated with this study is (1) a loss of confidentiality and (2) possible discomfort responding. This risk and our actions to protect study participants from the risk are discussed below.

1. To address concerns of breach of confidentiality, all electronic records will be stored on REDCap, a HIPAA-compliant electronic data format platform available through NYU Grossman School of Medicine. All files and will be kept confidential to the extent permitted by law. Records will only be available to research staff, and Federal, State and Institutional regulatory personnel (who may view records as part of the routine audits). Privacy will be protected through the use of codes (an ID number) rather than with identifying information so that in the unlikely case that materials are exposed, the subjects' identity is not disclosed. REDCap will be used to administer electronic questionnaires, with no identifying information appearing on the questionnaires. Participants' hard copy contact forms and ID logs will be kept in a locked cabinet on site. Source documents will be shredded in accordance with NYU Grossman Health policy regarding retention of data. All electronic data will be kept on password-protected computers. If results are published, only group information will be reported and they will not contain any identifying information about any individuals.

2. Participants may feel discomfort responding to some of the questions. To mitigate this risk, participants will be notified during consenting that they do not have to answer any questions that make them uncomfortable.

2.3.2 Known Potential Benefits

The benefits of participation in this study include an opportunity to help to determine the impact of Family Connectors as an educational/supportive intervention for family members of individuals with first episode psychosis, which in turn is hypothesized to improve adolescent/young adult functioning in key domains.

3 Objectives and Purpose

3.1 Primary Objective

The purpose of this study is to examine the association between involvement in Family Connectors, a manualized peer-to-peer support and education program for family members who participated in OnTrack, a treatment program for adolescents/young adults with first episode psychosis. A total of 96 family members will be enrolled in this study; of them, 48 will be randomly assigned to Family Connectors + a packet of community resources, and 48 will receive the community resource packet alone. Outcomes will consist of caregiver self-efficacy, strain, connection to services, satisfaction with the program, and functioning of the adolescent/young adult at school and work.

3.2 Secondary Objectives (if applicable)

N/A

4 Study Design and Endpoints

4.1 Description of Study Design

The study will employ a randomized controlled study design; a total of 96 family members who participated in OnTrack with their adolescent/young adult will be randomized to either Family Connectors or a waitlist comparison group. Data will be collected at baseline (upon the discharge of the adolescent/young adult from OTNY), a follow up (one-month post-baseline) and posttest (seven months post-baseline). For participants in the waitlist condition who choose to work with a Family Connector after their posttest, an identical posttest will be collected at the end of their 6-month intervention period. Both conditions will receive a packet of community resources.
We will conduct a single qualitative interview with each of the Family Connectors to get feedback on their experience as a Family Connector and receive suggestions for further modifications and improvements that can be made to the Family Connectors model.

5 Study Enrollment and Withdrawal

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. English speaking or Spanish speaking,
2. 18 years of age or older,
3. Family member of adolescents/young adults with first episode psychosis who participated in OnTrack.

For the qualitative interviews with our Family Connectors, all individuals working as Family Connectors will be eligible to participate.

For the qualitative interviews with family members, all inviduals who worked with a Family Connector, either initially or after their time on the waitlist and posttest, will be eligible to participate.

5.2 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Does not provide informed consent.

5.3 Vulnerable Subjects

No vulnerable populations will be enrolled.

5.4 Strategies for Recruitment and Retention

OnTrack staff inform family members about the study using the recruitment script and recruitment flyer which will be distributed as physical flyers and through the OTNY listserv along with study description. If interested, secure a document with their contact information and their agreement to be contacted by a member of the research team. Potentially eligible participant information will be forwarded to a member of the research team, who will provide greater detail about the study, determine eligibility, and answer any questions the potential participant may have. If the potential participant meets the eligibility criteria and is interested in participating, the research staff will review the consent form with the participant and secure informed consent via REDCap. The participant will complete the baseline assessment by phone.
Retention will be enhanced via gathering multiple phone numbers and having regular contact. Further, to

improve enrollment and retention, we will explain to potential subjects that everybody will at some point be eligible to get a Family Connector. Participants in the control group will have access to receive a Family Connector after the completion of their T3 assessment.

For the qualitative interviews with our Family Connectors, Family Connectors will be informed about the study during their weekly check-in with the research team. If interested in participating, the research staff will review the consent form with the Family Connector, titled the "Family Connectors Consent Form," and secure informed consent via REDCap. The participant will complete the interview by zoom.

For the qualititave interviews with family members, a member of the research team will contact every participant who worked with a Family Connector. If interested in participating, the research staff will review the consent form with the participant and secure informed consent via REDCap. They will be informed that the interview will be used to create a transcript and will choose whether or not they feel comfortable having the interview recorded. The participant will also have the choice to complete the interview either by Zoom or phone call.

5.5 Duration of Study Participation

Participants will be enrolled for approximately nine months post-study initiation (baseline to posttest), and up to 15 months if they are in the waitlist condition and choose to work with a Family Connector after the completion of T3.

The qualitative interview with our Family Connectors will take up to one hour.

The qualitative interview with family members will take up to one hour.

5.6 Total Number of Participants and Sites

We will aim for a total sample of 96 participants.

5.7 Participant Withdrawal or Termination

5.7.1 Reasons for Withdrawal or Termination

Participants are free to withdraw from participation in the study at any time upon request. An investigator may terminate participation in the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

5.7.2 Handling of Participant Withdrawals or Termination

If subjects decline at any time point, they will be considered withdrawn from the study and will no longer be contacted for the remainder of the study.

5.7.3 Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided

by the suspending or terminating party to NYU. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension. Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the sponsor and/or IRB.

6 Study Schedule

6.1 Enrollment/Baseline

Enrollment/Baseline Visit 1

- Verify eligibility
- Obtain signed informed consent from participants (see the Appendix).
- Collect baseline assessment

Procedures listed are consistent with those included in the Schedule of Events (Appendix A).

6.2 Intermediate Visits

Weekly phone calls by a Family Connector for between three and six months.

6.3 Final Study Visit

Final Study Visit 2

- Complete posttest assessment

Procedures listed are consistent with those included in the Schedule of Events (Appendix A).

6.4 Withdrawal Visit

If subject withdraws early or investigator terminates subject participation, the subject will no longer be contacted.

7 Study Procedures/Evaluations

7.1 Questionnaire Administration

Study measures include one questionnaire that taps into the following domains: (1) sociodemographic characteristics of the family member, (2) family member perceived self-efficacy, (3) family member/caregiver social support, caregiver strain, satisfaction with Family Connectors, and (4) the adolescent/young adult's functioning at school and work. The questionnaire will be collected via REDCap at three time points (with the exception of the sociodemographic questionnaire, which will be collected at T1 only, and satisfaction questions, which will be collected at T3 and T4 only).

See the Appendix for a copy of the measures.

7.2 Procedures/Evaluations

The measure will be administered at baseline (upon discharge from OTNY), one-month post-baseline (prior to intervention) and posttest (following the conclusion of the intervention). *For participants in the waitlist condition who choose to work with a Family Connector after their posttest, an identical posttest will be collected at the end of their 6-month intervention period.*

See the Appendix for a copy of the measure.

8 Safety and Adverse Events

8.1 Definitions

Unanticipated Problems Involving Risk to Subjects or Others
Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

Adverse Event
An ***adverse event*** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

Serious Adverse Event
Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

Preexisting Condition
A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

General Physical Examination Findings
At screening, any clinically significant abnormality should be recorded as a preexisting condition. At the end of the study, any new clinically significant findings/abnormalities that meet the definition of an adverse event must also be recorded and documented as an adverse event.

Post-study Adverse Event
All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

8.2 Recording of Adverse Events

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should recorded in the source document, though should be grouped under one diagnosis.

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period must be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to study participation should be recorded and reported immediately.

8.3 Reporting of Serious Adverse Events and Unanticipated Problems

8.3.1 Investigator reporting: notifying the IRB

Federal regulations require timely reporting by investigators to their local IRB of unanticipated problems posing risks to subjects or others. The following describes the NYULMC IRB reporting requirements, though Investigators at participating sites are responsible for meeting the specific requirements of their IRB of record.

Report Promptly, but no later than 5 working days:
Researchers are required to submit reports of the following problems promptly but no later than 5 working days from the time the investigator becomes aware of the event:

- ***Unanticipated problems including adverse events* that are unexpected and related**
  - *Unexpected: An event is "unexpected" when its specificity and severity are not accurately reflected in the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document and other relevant sources of information, such as product labeling and package inserts.*

- *Related to the research procedures: An event is related to the research procedures if in the opinion of the principal investigator or sponsor, the event was more likely than not to be caused by the research procedures.*
- *Harmful: either caused harm to subjects or others, or placed them at increased risk*

Other Reportable events:
The following events also require prompt reporting to the IRB, though ***no later than 5 working days***:

- ***Complaint of a research subject*** when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.
- ***Protocol deviations or violations*** (includes intentional and accidental/unintentional deviations from the IRB approved protocol) for any of the following situations:
  - *one or more participants were placed at increased risk of harm*
  - *the event has the potential to occur again*
  - *the deviation was necessary to protect a subject from immediate harm*
- ***Breach of confidentiality***
- ***Incarceration of a participant*** when the research was not previously approved under Subpart C and the investigator believes it is in the best interest of the subject to remain on the study.
- ***New Information indicating a change to the risks or potential benefits*** of the research, in terms of severity or frequency. (e.g. analysis indicates lower-than-expected response rate or a more severe or frequent side effect; Other research finds arm of study has no therapeutic value; FDA labeling change or withdrawal from market)

Reporting Process
The reportable events noted above will be reported to the IRB using a Reportable New Information submission and will include a description of the event with information regarding its fulfillment of the above criteria, follow-up/resolution, and need for revision to consent form and/or other study documentation. Copies of each report and documentation of IRB notification and receipt will be kept in the Clinical Investigator's study file.

9 Study Oversight

It is the responsibility of the Principal Investigator to oversee the safety of the study at her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan. Data safety monitoring will occur on an ongoing basis. There will not be any predefined stopping rules for the entire study, as it does not pose more than minimal risk for study participants.

10 Statistical Considerations

10.1 Study Hypotheses

Hypothesis #1: Family members who participate in Family Connectors (i.e., phone-based parent-to-parent support) will demonstrate improved outcomes at post-test and follow-up as measured by higher self-efficacy, greater perceived social support, and lower caregiver strain in comparison to family members who receive the comparison condition.

Hypothesis #2: Identified clients whose family members who participate in Family Connectors (i.e., phone-based parent-to-parent support) will demonstrate improved outcomes at post-test and follow-up as measured by functioning at school and work in comparison to the comparison condition.

10.2 Sample Size Determination

Our sample size was calculated based upon OnTrackNY's annual enrollment numbers; specifically, there are approximately 150 families who graduate each year from Family Connectors; based upon this number, we anticipate 96 will participate.

10.3 Statistical Methods

Univariate statistics will be employed to describe the sample characteristics. Categorical data will be presented in percentages; interval and ratio-level data will be presented via measures of central tendency and dispersion (e.g., means, standard deviations). Bivariate and multivariate analyses will be conducted in order to examine between and within group differences in outcomes.

11 Source Documents and Access to Source Data/Documents

Source data is all information, original records of clinical findings, observations, or other activities in a study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the study.

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB/EC, the sponsor, government regulatory bodies, and University compliance and quality assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities.

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

12 Ethics/Protection of Human Subjects

12.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

12.2 Institutional Review Board

The protocol, informed consent documents, recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent document must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented. An IRB reliance agreement will be completed for those sites who are not affiliated with NYU.

12.3 Informed Consent Process

12.3.1 Consent/Assent and Other Informational Documents Provided to Participants

A consent form describing in detail the study intervention, study procedures, and risks are given to the participant and documentation of informed consent is required prior to starting intervention. The consent form is submitted with this protocol (see the Appendix).

12.3.2 Consent Procedures and Documentation

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB-approved and the participant will be asked to read and review the document. The investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

A copy of the signed informed consent document will be stored in REDCap. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the subject's research record. Any alteration to the standard consent process (e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

12.4 Participant and Data Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization.

Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. This confidentiality is extended to all collected information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The study monitor, other authorized representatives of the sponsor, or representatives of the IRB may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and questionnaires for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information, consent forms, and ID logs will be securely stored for internal use during the study in separate locked file cabinets. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Department of Child and Adolescent Psychiatry. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by Department of Child and Adolescent Psychiatry research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Department of Child and Adolescent Psychiatry.

13 Data Handling and Record Keeping

13.1 Data Collection and Management Responsibilities

Data collection is the responsibility of the study staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change.

All data will be collected centrally on an ongoing basis by the investigation team electronically on REDCap, with no identifying information appearing on the questionnaires. Participants' name and other personal identifying information will be stored in an electronically secure database at NYU Langone Medical Center. Privacy will be protected through the use of codes (an ID number) rather than with identifying information so that in the unlikely case that materials are exposed, the subjects' identity are not disclosed. All study documents and data will be maintained in password-protected computer files. Only the investigation team will have access to the data.

Hard copies of each questionnaire will be kept as records for routine audits. Paper copies of documents will be maintained in locked file cabinets. Participant contact forms, consent forms, questionnaires and ID logs will be kept in a separate location in a locked cabinet. Source documents will be shredded in accordance with NYU Langone Medical Center's policy regarding retention of data.

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.2

13.2 Study Records Retention

Study documents will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

13.3 Protocol Deviations

A protocol deviation is any noncompliance with the study protocol or MOP requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents. Protocol deviations must be reported to the local IRB per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

13.4 Publication and Data Sharing Policy

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

14 Study Finances

14.1 Funding Source

This study is financed through a grant from National Institute of Mental Health (NIMH); P50MH113662.

14.2 Costs to the Participant

Subjects will not endure any costs as a result of participating in the study.

14.3 Participant Reimbursements or Payments

A $50 gift card incentive will be given to participants at each timepoint, for a total of up to $200 per participant.

A $50 gift card incentive will also be given to participants upon completion of the qualitative interview, meaning each participant could receive up to $250.

15 Study Administration

15.1 Study Leadership

The Study Team will govern the conduct of the study. The Study Team will be composed of the Study Chairman, the PI, the study Research Coordinator and Research Assistants. The Study Team will meet on a weekly basis.

Dr. Lawrence Palinkas will serve as a consultant in order to assist with the analysis of de-identified qualitative data. Dr. Palinkas is a Clinical Professor in the Herbert Wertheim School of Public Health and Longevity Science at the University of California, San Diego and an expert in mental health services research and implementation science. Dr Palinkas will have no access to PHI or NYULH locations. He has no conflicts of interest.

Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this study will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the study. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by the NYU Langone Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study. All NYULMC investigators will follow the applicable conflict of interest policies.

16 Attachments

1. Contact form
2. Consent form
3. Questionnaire
4. Farent Connectors manual
5. Resource Packet

Attachment A

Schedule of Events

Activity	Visit 1 (T1)	Visit 2 (T2)	Visit 3 (T3)
Study Team Procedures			
Informed Consent	X		
Assessment	X	X	X