# Family Engagement, Cross-System Linkage to Substance Use Treatment for Juvenile Probationers -- Phase 3

## NCT03048552

## Study Protocol
## 1/1/2016

**Study Protocol**

**Study Aims.** Working with two county probation departments that have adolescent SU services, we propose the following Specific Aims:

1. To examine, in a pilot-test, the impact of Family CONNECT on improving (i) cross-system (probation-SU agency) referral; (ii) family engagement; (iii) enrollment and retention of youth/families in SU treatment; and (iv) secondary outcomes of reducing youth SU and recidivism.

3. To elucidate multi-level factors (e.g., family, staff, and organizational-level) that influence implementation of Family CONNECT in probation settings to inform a larger trial.


**Overview of study design.** We propose to pilot-test a service delivery model for youth on probation that targets probation-, treatment system- and family-level factors to increase uptake of SU services; and to understand the organizational elements required to successfully implement this adapted model in juvenile probation settings (see Timeline in Budget Justification). Guided by the CFIR framework and GPM, **Pilot Test and Implementation Evaluation,** youth on probation (n=50) and their caregivers (n=50) will participate in a pilot of Family CONNECT to examine its preliminary impact on cross-systems referral, family engagement, and retention of youth/families in SU treatment. We will explore family-, staff-, and organizational-level factors that influence Family CONNECT feasibility, acceptability, and sustainability in probation settings (Year 2; Year 3, Months 1-6). Youth-caregiver dyads will be randomized at the level of probation officer (PO) to Family CONNECT or standard of care (SOC). Youth and caregivers will be assessed at baseline, and 2 and 6 months post-baseline. Probation staff will be assessed before implementation of Family CONNECT and at 6, 12 and 18 months post-training.

**Study location and participants.** The sample will be recruited from two county probation departments: Staffed by approximately 39 juvenile probation employees collectively with 600 youth annually: 65% male, 51% white, 32% African American, 11% Hispanic, mean age 15.0 years. Current SU screening, identification, and referral practices: Both departments screen all youth for SU and MH problems within the first month of assignment to probation supervision, using the validated Massachusetts Youth Screening Instrument-2 (MAYSI-2)[90] to identify potential behavioral health needs. The PO communicates SU treatment needs to the youth and family and makes needed referrals. Neither site uses any kind of cross-system linkage protocol, but both are aware of this need and extremely interested in filling this gap. Given current use of MAYSI-2, increasing use of evidence-based screeners and identification of youth SU is not an outcome of the proposed study, but will remain part of the Family CONNECT training (Section 3.3.7.2).

   *Inclusion criteria.* Youth: 10-17 years old; currently on probation; MAYSI-2 score of ≥4, indicating 'probable clinical significance,'[90] or documented evidence of problem SU or SU service need. Caregiver: legal guardian (birth parents, relatives, and adoptive parents; foster care parents cannot provide legal consent for their child to participate in research in NYS). Probation and SU treatment staff: currently employed at participating probation departments or SU treatment agencies. For Phase 2, youth inclusion criteria will be the same as in Phase 1, with the additional criteria that all youth must have been screened/identified as having SU problems as defined by a score of ≥4 on the MAYSI-2 but NOT currently and regularly attending SU treatment within the past month.

   **Exclusion Criteria:** Youth and caregivers: medical or psychiatric illness requiring hospitalization at the time; serious suicidal or homicidal ideation; or been placed on probation for a serious violent offense (to ensure the safety of participants and research staff).


**Pilot and Implementation Evaluation.**

**Recruitment and Enrollment.** Youth on probation (n=50) in Dutchess and Ulster County probation departments and their primary adult caregivers (n=50) will be recruited through PO referral using the recruitment procedures used in the formative phase. Interested caregivers will be asked to provide written permission and consent for youth and caregiver participation and youth to provide written assent. Although all POs will be involved in proposed study due to randomization at the level of PO, we will recruit POs with active caseloads (n=21) to complete brief assessment using the same recruitment procedures used in the formative phase. Considerable effort will be taken to ensure that youth and caregivers do not feel coerced to participate in Family CONNECT and staff do not feel coerced to complete assessments.

   *Enrollment and tracking.* During Year 1, a participant tracking system will be created using established strategies from our team's prior studies tracking SU youth and JJ-involved families. Data include contact information, 2-3 people who know how to contact them, regular requests for updates, ways to contact while maintaining confidentiality, etc. (Section 5, Human Subjects). We will send thank you notes after each interview,

personalized birthday cards to youth and caregivers if appropriate, and project newsletters. Families will be compensated for participation in accordance with standard remuneration procedures in this population.

*Randomization.* We will employ cluster randomization at the level of the PO using a computerized randomization program: 50% of POs at any given site will be assigned to Family CONNECT and 50% to SOC. All caregivers of youth with SU problems based on the MAYSI-2 but not currently in treatment will be informed about the study by the PO upon delivery of information that the youth requires SU treatment. Experimental and control manipulations are implemented in the same setting, and thus contamination may be an issue. However, cross-family interactions (e.g., in waiting areas) are not expected to result in significant contamination since families tend to have limited interactions with each other. POs in the experimental arm and Linkage Specialists will be instructed not to assist POs in the SOC arm in any way. POs randomized to SOC may experience decreased morale or a desire to increase performance to match POs in the experimental arm. To offset this, we will clearly articulate to the POs that the study is not an evaluation of their job performance but rather an evaluation of the potential added value that a Linkage Specialist confers with respect to increasing youth enrollment in SU treatment. Despite these precautions some contamination may occur. To identify any possible contamination, we will 1) collect process data from all POs on interactions with Linkage specialists and job satisfaction as part of our implementation assessment (Section 3.3.8.3) and also collect department-wide data on key referral and uptake outcomes for 6 months prior to the implementation of Family CONNECT to identify any changes occurring in the SOC condition (Section 3.3.8.1)

We chose to randomize at the level of the PO for three reasons: 1) Randomizing by youth would create situations where a PO was working both with youth assigned to Family CONNECT (and Linkage Specialist) and with youth in SOC with considerable contamination potential. 2) Randomizing by site with only two sites is arguably not randomization and would not permit us to separate considerable site effects from differences in the two arms. Although frequency matching of participants would minimize some site effects, the limits to recruitment would be too restrictive in this pilot. Randomizing by site would also give us only limited ability to examine system-level factors that influence implementation of Family CONNECT. 3) Conducting a pre-post design (no randomization) would incur temporal and historical effects (e.g., regression to the mean; changes in services policy), limiting our ability to infer a causal influence of Family CONNECT on our proposed outcomes.

**Family CONNECT.** Family connect will be adapted using protocols from CONNECT and TIES. In addition, based other successful models of embedded linkage or family support specialists[78,79], we will design Family CONNECT to be delivered by POs with a Linkage Specialist who is embedded in the probation department. There will be one Linkage Specialist at each study site who will have prior experience working with families/youth with SU/D problems and/or JJ involvement and hold a Masters degree in clinical social work or a related field. It is anticipated that s/he will assume the linkage and potentially the referral roles of the PO in CONNECT and conduct the engagement strategies originally conducted by a provider in TIES. POs will screen and inform youth and caregivers about any SU treatment needs; POs and Linkage Specialist will work with the research team during the training to develop standard protocols for referring youths to SU treatment and establish formalized relationships with partnering substance abuse treatment agencies.

*Protocol Training.* The Drs. Elkington, Wasserman, and McReynolds will train the POs and Linkage Specialists in three 1-day workshops. Workshops will review (1) adolescent SU and its correlated risks (e.g., recidivism, common co-occurring disorders), evidence-based treatments, and family role in risk and prevention; (2) how clinicians arrive at a DSM diagnosis, reviewing symptom profiles and criteria for SUD and other related disorders (e.g., PTSD) with substantially elevated prevalence in JJ youth; (3) screening for SU and mental health problems in youth; (4) effective communication techniques with behavioral health providers/agencies, establishing formalized relationships with partnering SU treatment agencies, and developing standard protocols for referring youths to SU treatment; (5) engaging families and youth, identifying barriers to treatment, and increasing motivation to access services; (6) coordinating with SU treatment agencies/clinicians to monitor youth progress and treatment retention. POs will join the first two training workshops, receiving training through topic #4. Linkage Specialists will receive additional training in TIES-derived intensive engagement strategies and monitoring techniques. Knowledge of these topics will be evaluated with pre and post-test training assessments.

*Protocol.* Following training, the PO and Linkage Specialist will establish memoranda of understanding with community SU treatment agencies. The Linkage Specialist will meet with the youth's PO after study enrollment. After identification of appropriate service agency(ies), the Linkage Specialist will refer the youth to a partnering SU treatment agency and other support services as necessary. S/he will meet with the family at the probation office and/or family's home to complete a family needs assessment and identify facilitators and barriers to treatment. S/he will use adapted TIES strategies to increase treatment motivation, decrease perceived barriers, and develop strategies to overcome practical barriers to attending treatment. The Linkage Specialist will be the liaison among the family, SU treatment provider, and youth's PO, addressing engagement problems with family and/or clinician, tracking youth attendance in treatment and informing the PO, and facilitating communication between the PO and clinician. The Linkage Specialist will track frequency of sessions and contacts and complete standardized process

measures to describe and evaluate each session or contact with families and providers (Section 3.3.8.3). The PI will supervise the Linkage Specialists weekly via phone/Skype.

## Outcome Evaluation

**Assessments.** Table 1 presents all measures, categorized according to outcomes defined in Aims 2 or by GPM or CFIR constructs with information on a) the domain/model construct and measure, b) the variable and measure psychometric properties, and c) time point administered and respondent (also see Appendix A for measures). Selected measures have been successfully used with JJS youth, SU youth or similar populations; the battery will be finalized following the adaptation of Family CONNECT.

**Implementation assessment.** A multi-method comprehensive framework approach will allow us to identify implementation features that promote optimal fit of Family CONNECT in the probation context. In addition to assessments in Table 3, we will develop the following assessments once the model is finalized. _Feasibility_: In addition to examining Family CONNECT's performance indicators, we will develop a TIES-based feasibility checklist measuring 3 types of program delivery obstacles: obstacles to youth/family participation (e.g., time, competing priorities); concrete obstacles (e.g., transportation); and site/ staffing obstacles (e.g., turnover, time/space constraints). Youth and caregivers will be assessed at 2 and 6 months post-baseline, and POs and Linkage Specialists at 6, 12, and 18 months post-training. _Fidelity:_ To assess the relationship between planned and actual implementation, we will design a checklist-based monitoring system with assessments completed by Linkage Specialists after each treatment agency referral, family session, or SU treatment provider/PO contact to quantify activities completed and next steps. Linkage Specialists will also record new circumstances that may influence the family system and threaten fidelity (e.g., loss/gain of employment; youth/family criminal involvement). _Acceptability:_ Linkage Specialists will complete a checklist evaluating their experience working in the probation department, with POs, and with SU treatment providers and usefulness of engagement strategies with youth/families. Probation staff will complete a measure assessing experience working with an embedded Linkage Specialist; perception of screening protocol as part of job description; and overall job satisfaction.

**Table 1. Family CONNECT Assessments**         **(BL=baseline; MIS=management information system)**

| Domain/Measures | Description/Variables/Psychometric properties | Time/*Respondent* |
|---|---|---|
| **Linkage and referral main outcomes** | | |
| **Referrals** | Count of youth referred to SU treatment | Pre-implementation; BL, 2 mos., 6 mos., *JJ agency MIS* |
| **Engage families/youth** | | |
| Evaluation of Probation Services Scale | 28 items; adaptation of Working Alliance Inventory (WAI)[100] to assess: 1) agreement on goals, tasks and development of bond with PO; 2) usefulness of services/referrals provided by probation department. Used in co-I Wasserman's prior work | BL, 2 & 6 mos. *Youth and caregiver* |
| Evaluation of Linkage and Referral Services Scale | 18 items; adaptation of Evaluation of Probation Services Scale to assess: agreement on goals, tasks and development of bond with Linkage Specialist. | Baseline, 2& 6 mos. *Youth and caregiver* |
| **Enroll and Retain** | | |
| Enroll | Count of youth who started substance use treatment (completed intake + 1 session) | Pre-implementation; BL, 2 mos., 6 mos. |
| Retain | Count of youth retained at least 6 weeks/4 sessions of treatment | *JJ agency MIS* |
| **Implementation Outcomes (see also Section 3.3.8.3)** | | |
| **Acceptability** | | |
| Client Satisfaction Questionnaire-8[101] | 8 items; assesses satisfaction and usefulness of services received. Validity and reliability have been well-established (α=.83-.93) | BL, 2 mos., 6 mos. *Caregiver* |
| Therapeutic Alliance Scale for Children-revised (TASC-r)[102,103] and for Caregivers (TASCP)[104] | 12 items; assesses alliance between youth and therapist (TASC-r) and caregiver and therapist (TASCP) in 2 domains: affective bond and collaboration on therapeutic tasks/goals. Good validity/reliability have been demonstrated (α=.81-.82 TASC; α=.85-.88 TASCP) | BL, 2 mos., 6 mos. *Youth and caregiver* |
| **Potential sustainability** Program Sustainability Assessment Tool (PSAT)[105] | 20 items; assesses: 1) political support; 2) partnerships; 3) organizational capacity; 4) program evaluation; 5) communications. Validity and reliability have been well-established (α=.79-.92) | Pre-implementation; 6, 12, 18-mos post-training *Staff, Linkage Specialist* |
| **GPM: Family predisposing and enabling factors; youth's SU treatment need** | | |
| **Youth SU/D** Global Assessment of Individual Needs (GAIN)[106] | Assesses SUD and frequency and quantity of alcohol, marijuana, and other drugs (e.g. cocaine, heroin, ecstasy) over past 30 days, year and lifetime. Well tested diagnostic tool for children and adolescents[107]. | BL, 2 mos., 6 mos. *Youth* |
| **Youth recidivism** | Count of youth (re)arrests and/or probation violations | 2 mos., 6 mos. *JJ agency MIS* |
| **Demographics** | 22 items; age, gender, race/ethnicity, family composition/structure, education, parental employment/household income, residential changes educational placement, justice involvement, primary caregiver. | BL, 2 mos., 6 mos. *Youth and caregiver* |

| Barriers to treatment | 44 items; 4 subscales of barriers to participation: a) stressors and | BL, 2 mos., 6 mos. |
|---|---|---|
| Barriers to Treatment Participation Scale[108] | obstacles; b) treatment demands; c) perceived relevance of treatment; d) relationship with therapist. Widely used in services outcome research and validity and reliability well-established (α=0.94.)[108] | *Caregiver* |
| **Motivation and perceived SU treatment need** Motivation for Youth's Treatment Scale (MYTS)[109] | 8 items; assesses intrinsic motivation for treatment with 2 subscales: problem recognition and readiness to participate in treatment. Psychometric properties have been established (α=0.84-0.89)[109] | BL, 2 mos., 6 mos. *Youth and caregiver* |
| **Service utilization** GAIN | Prior and current service utilization; type of services; frequency of service use; length of stay | BL, 2 mos., 6 mos. *Youth and caregiver* |
| **CJS and other system involvement** Demographics; GAIN | 6-items; assesses number of times youth's caregivers have been in jail or prison; age of youth first and last time Assesses youth removal from home; legal custody of youth | BL, 2 mos., 6 mos. *Youth and caregiver* |
| **GPM: Family predisposing and enabling factors; youth's SU treatment need** | | |
| **Caregiver SU/MH problems** Beck Depression Inventory[110] State-Trait Anxiety Inventory[111,112] Clinical Diagnostic Questionnaire[113] | Depression and Anxiety symptoms, PTSD and Substance Use Disorders. Use of well validated and reliable instruments, widely used in treatment and services research. | BL, 2 mos., 6 mos. *Caregiver* |
| **Family conflict/support** Family Environment Scale[114] | 18 items; assess family functioning: cohesion and conflict. Well validated, used with delinquent youth (α=0.61-0.78).[114,116,117] | BL, 2 mos., 6 mos. *Youth and caregiver* |
| Caregiver Strain Questionnaire-Short form[115] | 7-items; assess strain caregiver experiences providing for a youth with behavioral health needs. Subscales =objective & internalized strain; validity and reliability well-established (α=0.82-0.90)[118] | BL, 2 mos., 6 mos. *Caregiver* |
| **CFIR: Inner setting and characteristics of individuals** | | |
| **Organizational and staff characteristics** National Criminal Justice Treatment Practices (NCJTP) survey[119] | 1) mission and goals of correctional programs; 2) organizational climate and culture for providing services; 3) organizational capacity and needs; 4) opinions of administrators, staff regarding rehabilitation, punishment, and services provided to offenders; 5) treatment policies and procedures; and 6) working relationships between correctional and other agencies. Psychometric properties established[119] | Pre-implementation; 6, 12- and 18-mos. post-training *Staff and Linkage Specialist* |

**Data Management and Analysis.**

**Primary data analysis overview.** A primary goal of this pilot study is to prepare for a large scale trial of Family CONNECT by determining important parameters with sufficient accuracy to allow reliable estimates of sample size and power for the subsequent study. Key study parameters include means and standard deviations for continuous endpoints (e.g. number of referrals); proportions for dichotomous endpoints (e.g. youth enrolled in services); response profiles for longitudinal studies (e.g. performance improvement or degradation); potential mediators of service delivery model outcome (e.g. perceived need for treatment); and potential correlates of implementation outcomes (e.g. organization culture; staff attitudes; treatment motivation). Estimation of design parameters with point and confidence interval estimates will be considered highly important. Large sample sizes are not required to locate these parameters approximately, but adequately, for planning the subsequent trial; tests of study hypotheses in this pilot will likely not have sufficient statistical power. Therefore, consistent with the R34 mechanism, a key role for statistical planning of this pilot study is to ensure that the critical parameters for the larger trial are estimated as accurately and as informatively as possible. Certain principles then follow: (1) If alterations are necessary to address measurement or performance problems, these will be permitted in an effort to establish optimal procedures and design parameters before a future trial, precisely so that no changes in protocol will be required during a future trial; and, (2) Estimation of critical design parameters with point and confidence interval estimates will be considered highly important, as large sample sizes are not required to locate these parameters adequately when planning for a subsequent trial. As a result, we are not powered to estimate small effect sizes or carry out sophisticated statistical analyses; rather, we seek to estimate key study parameters with sample means and proportions with two-sided 90% confidence intervals.

Number of youth enrolled in treatment within the past 6 months is the <u>primary </u>outcome of the service delivery model, assessed at 6-months post baseline. Other linkage and engagement variables that will be examined include: number of youth with SU problems referred for treatment (referral), working alliance between family and PO and family and Linkage Specialist (engagement), and number of youth retained in treatment for at least 4 sessions/6 weeks (retention). Implementation outcomes that will be examined include feasibility, acceptability and potential sustainability. In addition, potential correlates of implementation as specified by the CFIR will be examined, such as organization culture and climate, staff attitudes, agency interconnectedness. Finally, mediators associated with service use that are specified by the GPM model will also be examined, including motivation for treatment, perceived barriers to treatment, caregiver SU problems. As noted in Table 3, this study yields many variables. We, thus, focus on a few of primary interest to illustrate our analytic approach. <u>Attrition and missing data</u>. Based on the PIs K01 award, we anticipate minimal attrition (~15%). We will compare those who did versus did not complete FU on key predictors from the baseline assessment to check for possible bias.

**Analysis Plan for Specific Aim 2.** Prior to conducting our multivariate analyses, we will examine study

variables using descriptive statistics and test for differences across demographic characteristics (e.g., race/ethnicity, age, education) using t-tests, ANOVAs, and Chi-squares, as appropriate. As participants will be randomized into two groups (at the level of the PO), systematic baseline differences are not expected; however, in the event that some parameters differ across conditions at baseline, they will be included as covariates in subsequent multivariate models. We will calculate descriptive summary statistics corresponding to the study variables at each follow-up (FU) to understand any temporal patterns, as well as compare the two groups in terms of average change from baseline to 6-months post-baseline (averaged across 3 time points).

We will use the general framework of generalized linear mixed models (GLMM) to model the longitudinal outcome trajectories[123-125]. Note that some of our outcomes are binary, some count and some continuous traits and thus need to be treated differently. The general form of the GLMM will be $(\mu_{ij}) = \beta_{0i} + \beta_{cov}\,Covariates_{ij} + \beta_{time}\,Time_j + \beta_{Trt}\,Trt_i + \beta_{Trt\,x\,time}\,rt_i \times Time_j$, where $\mu_{ij}$ is the mean response corresponding to subject $i$ on time $j$ (baseline and two follow-ups), g denotes the link function (identity for continuous outcome, logit for binary outcome and natural log for count outcomes); $Trt_i$ =1 if the i-th subject is in the FAMILY CONNECT group and 0 if the i-th subject is in the SOC group. The variable can be coded in different ways depending upon how one wants to model the effect of time on the mean response. For example, for characterizing only pre vs. post effect time can be coded as a binary indicator with 0 representing baseline and 1 representing post-randomization; Assuming a linear time trend, time can be coded as 0,1,2 or it can be simply coded as a categorical variable representing the distinct effect of each FU as compared to the baseline. The interaction coefficients $\beta_{Trt\,x\,Time}$ are of interest, measuring the difference in the rate of change in outcome across the two treatment groups at each follow-up assessment. If the baseline outcome measure is included as a part of the covariates on the right hand side of the above equation, then we only have three repeated measures on the left hand side of the model (j=1,2) and we can look at average treatment effect across visits without including the $Trt \times Time$ interaction term. In this particular case, the GLMM analysis with continuous outcome will be equivalent to a repeated measures analysis of covariance after adjusting for baseline values. The subject-specific random intercepts $\beta_{0i}$ are assumed to be normally distributed with a common variance, and they account for within-person correlation. Maximum likelihood estimation will be used for fixed effect parameters. Models will be compared according to information criterion like AIC, BIC. For some binary outcomes, we will perform an aggregate analysis after collapsing across the repeated measures using simple logistic regression comparing whether the probability of being enrolled in services over the entire FU period is different across treatment groups, after adjusting for baseline values. To ensure robustness, we will also apply an exchangeable working correlation structure to its corresponding generalized estimating equation (GEE) model. For the purposes of this R34 we will examine key study parameters within these three domains:

_Domain 1 (enrollment and retention outcomes):_ Differences between youth involved in Family CONNECT and those in the SOC comparison condition with respect to the following variables at 2- and 6-months post baseline: a) youth who began SU treatment (y/n) (completed intake + attended 1 session); b) youth who attended 4 sessions/remained in treatment for 6 weeks (y/n); c) total number of SU treatment sessions attended.

_Domain 2 (cross-system referral and engagement outcomes):_ Differences between youth and families involved in Family CONNECT and those in the SOC comparison condition with respect to the following variables at 2- and 6-months post baseline: a) youth referred to SU treatment (y/n); b) youth/caregiver engagement.

_Domain 3 (secondary outcomes):_ Differences between youth and families involved in Family CONNECT and those in the SOC comparison condition with respect to the following variables at 2 and 6 months post-baseline: a) youth (re)arrest (y/n); youth probation violation (y/n); c) any SU (y/n) and d) frequency of SU in past 30-days

**Analysis Plan for Specific Aim 3.** Using our theoretically informed model (see Figure 1) as a blueprint[126], we will use SEM to begin to unpack what theoretical constructs and pathways were influential in the intervention, and aid us to refine our conceptual model for the larger RCT. For example, it is possible that Family CONNECT will have more positive effect on service referral and engagement outcomes when operating in a probation department that is more supportive innovative concepts. Here, organizational culture would appear to modify the impact of Family CONNECT on youth service referral and engagement outcomes. We will examine the Lagrange Multiplier and Wald Tests to consider the deletion or inclusion of paths[127]; ultimately, however, the deletion or inclusion of paths will be informed by theoretical underpinnings. Once the model is identified, we will test for group differences between intervention conditions in latent constructs and in the proposed paths between these constructs. This method will allow us to estimate the intervention effects on the constructs directly as well as their relationships to one another.[128] We will use three goodness-of-fit indices: Bentler-Bonnet's Normed Fit Index, Bentler-Bonnet's Non-Normed Fit Index, and the Comparative Fit Index. We will also verify the root mean-square error of approximation (RMSEA) as an index of misfit. Well-fitting models will have fit indices of .90 or higher and <.06 for RMSEA.