

# Cover Page for ClinicalTrials.gov

<b>Official Study Title:</b>	A Pilot Trial of a Network Intervention for Youth After Incarceration
<b>NCT Number:</b>	NCT03556618
<b>Document:</b>	Statistical Design
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## **STATISTICAL DESIGN AND POWER**

### **Analytic Strategy**

For each of the aims, we will compare participants who received WPC pre-release services (control group) to participants who received WPC pre-release and post-release services (intervention group). To address possible differential uptake or attrition, we will also conduct treatment received analyses, using the percent time young people participated in the post-release program (9 months total for the initial cohort and 6 months total for the final cohort) as the predictor of outcome. We will also examine for balance on sociodemographic variables and other characteristics of interest between the intervention and control groups as a means of examining for selection bias. To address missing data, in the main analysis, we will use generalized mixed effects model for repeated measures, under the missing-at-random assumption. In addition, using multiple imputations with pattern-mixture models, we will conduct sensitivity analyses to investigate whether our findings are robust to the missing mechanisms (i.e., assuming missing-not-at-random). In particular, we will consider a scenario which is least favorable to the intervention arms; that is, a scenario where the missing observations in the intervention arm follow the same pattern as the one in the control arm.

#### **Aim 1: Measure the impact of the WPC Reentry intervention targeting recently incarcerated young people on decreasing rates of 30-day use and risky use of marijuana, alcohol, and other drug use.**

*Hypothesis 1:* Young people receiving the WPC intervention will have less substance use at follow-up (3 and 9 months for initial cohort, and 4 and 6 months for final cohort) compared to their in the control group.

For the main outcome, percentage of days used marijuana in the last 30 days, we will conduct a linear mixed effects regression model to account for repeated measurements within individual young people. We will perform unadjusted and adjusted comparisons, controlling for baseline demographic (race/ethnicity, age, parental SES) and substance use characteristics, as well as any variables found to be differential between the intervention and control groups. Similar analyses will be carried out to examine the impact of WPC on percentage days used alcohol and other drugs, and risky use of marijuana, alcohol, and other drugs. We will estimate the treatment effect on marijuana use with the adjustment of incarceration based on the principle stratification analysis.

#### **Aim 2: Test whether the WPC Reentry intervention decreases recidivism, increases receipt of behavioral health services, improves mental health, and enhances school and work engagement (secondary outcomes).**

*Hypothesis 2:* Young people receiving the WPC intervention will have less recidivism and mental health symptoms, and higher rates of receipt of community behavioral health services and school and work engagement.

For each of the secondary outcomes, recidivism, mental health symptoms, receipt of behavioral health services, and school and work engagement, we will conduct generalized linear mixed effects regression models to account for repeated measurements within individual young people, while controlling for baseline demographic and substance use characteristics, as well as any variables found to be differential between the intervention and control groups. We will also evaluate whether there is effect modification by baseline mental health symptoms, using interaction terms with the exposure variable in the regression analysis.

#### **Aim 3: Examine whether recently incarcerated receiving the WPC intervention report healthier social networks (lower proportion of peers engaging in risky behaviors and a higher number of supportive adults) than control young people.**

*Hypothesis 3:* Young people receiving the WPC intervention will have a lower proportion of peers engaging in substance use and a higher number of supportive adults in their social networks, compared to young people in the control group.

Regardless of whether WPC lowers drug use, recidivism, or use of support services, the social network analysis of reentry young people will give valuable information on changes in social networks among recently incarcerated young people during reentry. In addition, WPC is designed to encourage prosocial peer network formation, and the social network analysis will help determine why the intervention did or did not demonstrate the expected effect. Understanding strategic levers for how young peoples' social networks can be altered is critical to developing sustaining solutions to young people substance use and incarceration. We will measure how social networks function for young people and whether the insertion of a supportive adult can create linkages to substance use services and promote healthier social networks. We will use the approach described in Baron and Kenny (1986) to evaluate whether our data are consistent with a model in which social networks mediate the relationship between WPC receipt and substance use. Additionally, if analyses for Aims 1 and Aim 2 do not indicate improvement overall in the intervention group, we will conduct exploratory analyses to identify subgroups of young people whose Aim 1 and Aim 2 outcomes improve and examine their social networks.

Primary social network measures will include the change in proportion of peers using substances (alcohol, marijuana, other drugs), limited to those whom the subject interacts with within the last month. We will compare baseline social network characteristics of the intervention and control groups and control for these measures if significant differences are noted. To test whether young people receiving WPC report a lower proportion of peers in their network engaging in substance use, we will conduct a mixed effects binomial logistic regression model accounting for repeated measurements within students. We will control for baseline demographic characteristics, as well as any variables found to be differential between the intervention and control groups. We will also examine the number of non-using supportive adults in their network using a mixed effects binomial logistic regression model. Finally, based on young peoples' descriptions of the connections between alter-alter pairs, we will construct a measure of peer network density (number of alter-alter connections out of total possible) for the peer substance-using and non-using networks. We will use mixed effects models to investigate whether network structure differs between study arms and whether intervention young people report stronger connections to healthy peers and adults.

### **Sample Size Estimate**

We estimated power for a 2-arm pilot trial. We plan to recruit and consent 160 transition-age young people exiting jail. With a sample size of 160, we believe that our study will be adequately powered to detect a minimal detectable difference in the percentage of days used marijuana in the past 30 days of 17%, which is equivalent to a decrease of 5 days of marijuana use in a 30-day period. This difference is within the observed effect seen in a prior study of marijuana use among reentry young people, which found a range of intervention effects from 11% to 38%. This calculation assumes 10% attrition rate at 3 months, two-sided test with alpha 0.05, and 80% power.