STUDY PROTOCOL

Social Behavioral Template

Recovery Finance: Financial Health and Mental Health After Incarceration

IRB#2000033658

Protocol Version

February 20, 2024

VERSION # 003

Clinical Trials Registration Number (if applicable)

Confidentiality Statement:

Synopsis

Purpose

This proposal will address financial wellbeing, an often overlooked but important factor impacting reentry for justice-involved people with mental health challenges, who are disproportionately Black and Latinx. The project will change community level determinants by integrating financial capability support (one-on-one coaching and access to financial tools and services) into existing services and training bank and credit union staff to reduce discrimination. It will also support collaborative community efforts working towards upstream policy and legal reforms to reduce the incidence of those financial challenges.

Objectives

This research project will use Community Based Participatory Research (CBPR) methods to achieve the following specific aim:

1) Change community level determinants that impact financial well-being and health of the target group by training existing service provider including: i) community-based financial capability providers to be able to address financial difficulties of the target group; ii) service providers along the criminal justice pathway to be able to provide basic financial guidance to target group; iii) financial institution staff to reduce discrimination related to financial consequences of justice-involvement and mental illness. We will also support community collaborations working for legal/policy reform that impacts finances of target group.

2) Use mixed methods to assess impact on community determinants, measuring integration of financial capability support into existing services, ability of financial coaches to support target group, access to financial products, attitudes, knowledge and behavior of bank staff, strength of community collaborations, and progress towards changes in laws and policies.

3) We will assess impact on individuals by measuring target mechanisms (financial skills, self-efficacy and behavior) hypothesized to mediate the relationship between financial capability support and primary outcomes including financial well-being and other health determinants (employment, housing, social support, mental health supports, and belonging), secondary outcomes (health and recidivism) and mediators between primary and secondary outcomes (hope, empowerment, and mastery).

4) Assess the value of integrating peer support into community-based financial capability support for the target group by randomizing participants into two groups, financial capability support only, or financial capability support plus peer support.

Study Population

The target population is persons 18 years of age or older who have been released from prison 24 months ago or less, who have mental health challenges and are interested in receiving financial guidance and live in or use services in the city of New Haven. As well financial coaches, bank staff, and criminal justice providers who provide services for people released from jail or prison.

Number of Participants

This research study plans to enroll 204 people. Participants will be randomized in two arms N=102 participants per arm for two arms for a total of N=204.

Study Design

This project will test a community level intervention to address financial difficulties of people who are justice-involved, low-income and have mental health challenges, in a setting where this population is disproportionately Black and Latinx. The study will assess whether training service providers and staff of financial institutions and supporting community collaborations results in greater availability of community level services, reduced local structural discrimination and increased community resources. An individual component of the intervention will involve a randomized control trial of participants receiving FCS with participants randomized to receiving additional peer support or not. The mixed-methods assessment will include validated quantitative measures, qualitative interviews, focus groups, and participantobservation. Integration of data sources across quantitative or qualitative measures will allow for a contextualized understanding of the impact of the Recovery Finance intervention on community level determinants of health. CBPR methods will be employed throughout the research to provide ongoing feedback about research design and implementation, study results, and interpretation.

Conceptual model. Our conceptual model posits that people who are justice-involved and have mental illness, who are disproportionately Black and Latinx, suffer from structural violence associated with poverty, discrimination, racism, including being excluded from financial services, and dealing with the financial costs of incarceration, as well as associated social determinants of health. This project will intervene at the community level through a continuous CBPR process, involving regular community meetings and consultation. Community/societal level: Activities at the community level will include: i) Training financial coaches to provide FCS to the target group; ii) Training people who provide services along the criminal justice pathway to provide basic financial support as part of their ongoing work with the target group; iii) Training bank and credit union staff to understand the causes of the financial difficulties faced by the target group, and how access to financial services can help to address thosedifficulties, and, iv) Supporting community collaborations to address legislative and regulatory policy reform.

We hypothesize that these community level interventions will result in changes in community determinants, including greater availability of services (FCS integrated into service system), reduced local structural discrimination (less discrimination among financial institution staff), and more community resources (greater availability of safe and affordable financial products, more effective community collaborations). We also hypothesize that more effective community collaborations will impact societal level outcomes through influencing policies and laws, but most likely these changes will not have a measurable impact on financial well-being and distal outcomes during the project period. Individual level: As a result of changes in community

Study Duration

The research study duration is planned four years after IRB approval, 8/31/2026.

Outcome Variables

This research study proposes to use the following outcome variables:

Convening a Community Advisory Board to identify stakeholders to help in refining, recruitment, and study design as part of the CBPR process. Sequential Intercept Mapping will be used to identify intercept points at which to intervene to help people with behavioral challenges who are justice involved and try to divert them from the system. SIM workshops will be used to identify where financial difficulties arise as a person moves through the system. Co-design workshops will be used to finalize the design of the project. Implementation of service provider training about structural roots of financial challenges.

In Phase II the following outcome measures will be used:

Community Outcomes: Pre and post analysis will be conducted to determine differences between pre and post intervention.

Societal Outcomes: Policy and legal reforms resulting from community collaboration will be documented from community meetings and activities.

Individual Outcomes: The research will use qualitative interviews (N=18), participant observation utilizing ethnographic methods such as Rapid-Assessment Ethnography and quantitative interviews. Primary outcomes include financial skills, financial self-efficacy, financial situations, financial well-being, employment, housing, social support, sense of belonging, and mental health supports. Secondary outcomes include physical health, psychiatric symptoms, substance use, and recidivism.

Locations/Facilities
The research will take place in the city of New Haven community and the offices of the Yale University Program for Recovery and Community Health.

APPROVED BY THE YALE UNIVERSITY IRB 3/13/2024

Abbreviations

Abbreviation	Explanation
CBPR	**Community Based Participatory Research**
CAB	**Community Advisory Board**
SIM	**Sequential Intercept mapping**
CFBP	**Community Financial Protection Bureau**

Glossary of Terms

Glossary	Explanation

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Protocol Revision History

Include the IRB approved protocol version number and date for each revision of the protocol. All version history should remain in the table and never be deleted. The oldest IRB approved version of the protocol should be listed on the top row. The most recent IRB approved version should be listed on the bottom row.

Version Date	Summary of Substantial Changes
09/11/2022	Initial protocol submission
07/06/2023	Modification to reflect increase in CAB meeting stipend payment
02/20/2024	Modification to reflect the increase of time for eligibility, from 12 months prior to interview date out of prison to within 24 months prior to interview out of prison. Also added the recruitment flyer.

1 Background

1.1 Background

Many individuals who have been incarcerated experience financial difficulties that contribute to a vicious circle of recidivism and poverty, particularly among our target group, minoritized populations who are already financially disadvantaged. Support for people leaving incarceration often includes help finding employment income or connection with disability benefits. Such support is crucial, but by itself does on address the multiple financial challenges faced by people who have been incarcerated, that by itself does not address the multiple financial challenges faced by people who have been incarcerated, that contribute to recidivism and perpetuation of poverty, and are also more prevalent among minority populations. Those challenges include problem debt, poor credit, and lack of effective access to banking services.

Incarceration and debt: People who have been incarcerated have high rates of what we term 'problem debt' - unsecured debt, high-cost auto-loan debt, unpaid bills including Legal Financial Obligations (LFOs) and personal debt; such debts are higher among people of color. Such debts may be relatively small in dollar amounts, but have serious negative consequences, including for health. Meanwhile, this group has less wealth-enhancing debt, such as mortgages, affordable auto-loan debt, student loan debt and business debt, than others; if they have such debts, they are more likely to be in arrears. They also have high rates of child support arrears. These financial problems often predate criminal justice involvement, particularly among our target group, but are made significantly worse when a person is incarcerated, as they are unable to effectively manage their finances, pay bills, and make payments on existing debts, resulting in arrears and damaged credit scores. Additional debts accumulate to pay for in-prison costs. After release, given difficulties finding employment and damaged credit, which increases the cost of borrowing, debts can worsen, and credit is further damaged.

Incarceration and credit: People in prison see their credit scores drop by 42-57 points on average; lower scores mean significantly higher interest rates, and less access to wealth-building debt. People of color have significantly lower credit scores, regardless of incarceration. High rates of identity theft among incarcerated people also damage credit.

Incarceration and banking: People who have been incarcerated are less likely than others to have bank accounts, relying instead on 'Alternative Financial Services' (AFS) such as prepaid cards, check-cashers, rent-to-own stores, and pawnshops, costing on average $2,400 annually. Our target group is more likely to be unbanked even prior to incarceration, due to fees, discrimination, and mistrust; AFS providers are often trusted more despite higher costs, in part because those costs are transparent and predictable, unlike bank fees. After incarceration, unbanked rates increase further due to lost ID, unpaid overdrafts, confusion, and discrimination. Many lenders require borrowers to have two years of uninterrupted employment and credit history. People without a bank relationship cannot access wealth-building debt and have limited options to build their credit, further perpetuating the cycle of poverty.

Financial difficulties caused by incarceration negatively impact health: Problem debt, including from LFOs, lack of savings, and AFS use are associated with negative health outcomes including psychological distress, depression, psychosis, suicidality, stress and anxiety, and skipping mental health appointments, as well as a range of physical health problems. People with mental illness with such financial difficulties face barriers to recovery, including stress and anxiety. Low credit scores are associated with psychosocial stress and overall negative health.

Incarceration-related financial difficulties affect employment, housing, social networks, and sense of belonging: Financial problems related to incarceration negatively impact employment and housing outcomes, social network support, and feelings of belonging, all of which are important health determinants.

Impact on employment: Discrimination against people with criminal records is a key reason for high unemployment, but debt and credit problems may also play a role, through background credit checks, wage garnishing that can impact willingness to work, and inability to borrow to purchase needed items such as a vehicle.

***Impact on housing*:** People who have been incarcerated are almost ten times more likely to be homeless or housing insecure; in addition to discrimination against people with criminal records, landlords often deny housing to people with poor credit.

Impact on social networks: People who are in debt, particularly if unemployed or unhoused, rely more heavily on social networks already stressed by the loss of income and other costs of the person having been incarcerated, resulting in social network members themselves facing financial difficulties including debt.

Impact on belonging: Problem debt is associated with shame and feelings of failure. credit has become a marker of social belonging and is associated with feelings of social membership and self-worth. recently incarcerated people see having a bank account as a sign of maturity.

Incarceration-related financial difficulties are associated with criminal justice involvement/recidivism*:* We know income is associated with recidivism, but other aspects of finances are also relevant.

Debt, credit, and recidivism: LFO debt is associated with recidivism, and there is a mutually reinforcing association between debt and crime. Credit is associated with recidivism: people who have been incarcerated are 20% more likely to recidivate if their credit was damaged during incarceration.

Employment, housing, social networks, belonging and recidivism: The association between debt, credit and recidivism may operate in part, through the impact of debt and credit on employment, housing, social networks and belonging, all of which are associated with recidivism.

Banking and recidivism: Being banked may impact recidivism via its connection with social belonging, as well as credit and debt; without a banking relationship it is impossible to access many types of loan and is extremely difficult to build credit.

Health-disparity populations are disproportionately impacted: Black and Latinx people with low incomes, and people with mental illness are disproportionally

incarcerated; and more likely to have financial difficulties, regardless of incarceration. Due to structural racism that has historically and continues to impact finances, Black and Latinx people have lower incomes, far less wealth (assets, savings), more problem debt and or more arrears or default on all types of debt lower credit scores and are more likely to be unbanked. People with mental illness also have lower incomes, less wealth, more problem debt arrears, worse credit and are more often unbanked than others; this project's PI, Dr. Harper has studied this issue extensively.

Covid-related financial benefits and debt relief reduced debt and improved credit for many, but racial and ethnic disparities persist and there is evidence that AFS borrowing increased. Black and Latinx people who have been incarcerated face greater difficulties than others obtaining housing and employment; the same is true for people with mental illness; and recidivism rates are higher for both groups.

Strategies exist to address financial difficulties: Financial capability interventions can reduce financial difficulties such as those faced by our target group and have been shown to positively impact health. Interventions include one-on-one coaching and connection to appropriate financial products, integrated into existing services. Some efforts have been made to adapt these interventions to meet the needs of this project's target group, people who are justice-involved and have mental health challenges, who are disproportionately Black and Latinx, but we know too little about how to operationalize such interventions effectively, or their impact on health or recidivism outcomes for this group. This project will help to rectify this lack of knowledge.

1.2 Prior Experience (if applicable)

Preliminary research, including by PI Harper, suggests that adapted FCS can be effective for criminal-justice involved people with mental health challenges: There is evidence that people who have mental illness and who have been incarcerated can benefit from FCS adapted to their situations, including financial coaching and access to and support with bank accounts. ***Financial guidance can be helpful for people who have been incarcerated:*** People who have been incarcerated have lower levels of financial literacy than others. Numerous recommendations have been made to include FCS both inside prison and after release, to improve reentry outcomes, including help with credit repair. People who are incarcerated are interested in receiving help to improve their financial knowledge. A financial literacy program for males in a work release program (n=180) improved participants' subjective and objective financial knowledge, understanding of banking, and financial attitudes. Financial education and credit counseling provided to women in prison (n=300) increased financial self-efficacy and self-empowerment, and the ability to identify and access financial resources in the community. FCS materials for people with incarceration histories have been adapted and or created specifically for this population, such as checklists for addressing debt and credit, including by PI Harper

based on the findings of her study of the financial challenges faced by people with mental illness recently released from prison.

A***ccess to bank accounts and other financial products after incarceration is possible and can be helpful:*** People who have been incarcerated are mistrustful of banks and afraid of fees and may be afraid of account garnishing if they owe child support or other debts, but studies have shown that trusted persons can encourage people to make financial decisions, including opening a bank account. While some financial institutions refuse to open accounts for persons who are or have been incarcerated there is no state or federal law requiring this. Regulations require that a person shows ID before opening an account (many in our target group lack ID), but have discretion regarding whether or not to accept prison ID. Many of our target group are denied accounts due to past unpaid overdrafts, but this too is an organizational level policy; financial institutions can open accounts for persons with past unpaid overdrafts, unless it arose from fraud. Studies have recommended that financial institutions collaborate to address barriers faced by formerly incarcerated people and take steps to change the culture and attitudes of bankers. Pennsylvania's State Department of Banking and Securities collaborated with the Department of Corrections to provide financial guidance and access to accounts for people during and after incarceration. We hope to encourage a similar collaboration in Connecticut. Outside mainstream banking, fintech companies are developing targeted financial products. In 2021, after research revealed the extent to which justice-impacted people are excluded from financial services, the Financial Solutions Lab invested in fintech start-ups seeking to help this group. These include online bank accounts targeted to the formerly incarcerated, small dollar credit building loans, a risk-assessment tool for landlords, employers, and lenders to assess the risk of people with criminal records more fairly, and debt dispute technology. In short, there are numerous opportunities to improve access to bank accounts and other financial products for people both during and after incarceration.

PI Harper's work indicates the complex financial difficulties faced by people who have mental illness and have been incarcerated, and the potential for tailored F S to address those difficulties. See table below:

'Alejandro' had found a job after being released and was planning to buy a car to be able to get a better job. However, his credit was extremely bad, due to multiple bills that had gone unpaid while he was in prison, including child support, utilities, and a large bank overdraft; he said that some of the bills were due to identity theft. He tried his best to work on his debts and credit but could not make headway. One barrier was the high amount of child support that was taken out of his check every month.	*Alejandro could have been advised to close all his accounts, including freezing his child support, before or soon after going into prison. After release, a financial coach could have helped him address the identity theft, negotiate with creditors, repair his credit, save for a deposit, and find an affordable car loan option.*
'Jim', a 24-year-old Black man who receives SSI, explained that during his last stay in prison his SSI, which was being paid into a bank account, was discontinued after 2 months. On release, he was unable to access his account as he had lost his ID and could not remember any of his log-in or passwords. He is living in transitional housing so has no immediate need for money. His SSI has recently been re-instated and continues to be paid into his bank account. Jim is extremely anxious that, combined with the SSI that was paid into his account while he was in prison, any new payments may take his balance over $2,000, which will result in his SSI being discontinued.	*Jim's discharge plan could have included verification that he was able to access his bank account after release. On finding that he wasn't able to access it, a financial coach could have helped Jack either to use his prison ID to access the account, or obtain alternative ID.*

'Carlos' explained that he had found out a few months after release that phone and utility accounts had been opened in his name while he had been incarcerated, and he now owed $1,000s in arrears. He was struggling to pay current bills for his new family and struggled to manage his anger about the identity theft. He also said that it was a struggle to manage his current bills, as had never had to pay such bills before going to prison, when he had been a successful drug dealer and other people had taken care of bills.	*Carlos could have been advised to freeze his credit soon after being incarcerated, to check his credit score regularly while in prison, and received financial coaching to help him learn how to pay his bills after release.*
After many years of repeated incarcerations and traumatic abuse, 'Theresa' was receiving disability benefits and was beginning to imagine a more stable future, including her own apartment. However, she was certain that her unpaid utility bills from the past would make that impossible, and as a result had decided that imagining having her own apartment was unrealistic.	*Theresa could work with a financial coach to determine whether she had unpaid bills, address any debts, and start to build credit to be able to get an apartment one day.*
'Sandra' had spent so much money paying for phone calls and putting money on her boyfriend Jack's books in prison, that she had fallen behind on her utility bills and her car payments. When he was released, she was resentful at having got into financial difficulties on his behalf, and ended the relationship despite, she said, still loving Jack. Without the support he had been expecting from Sandra, Jack returned to his old friends, and start selling drugs again, and was soon re-incarcerated.	*Thankfully, the law has changed such that Sandra would no longer have to pay for phone calls, though other in-prison expenses are still significant. A financial coach could have helped Sandra to plan her finances to be able to put money on Jack's books without falling behind on other bills, though this depends on Sandra's income and other expenses.*

Our team has conducted preliminary work on FCS for people with mental illness, peopleof color, and peoplewithhistoriesofincarceration: PI Harper has done extensive preliminary work relevant to this project's intervention at both the individual and community level. Harper directed a NIMH 34 mixed methods study (PI-Dr. owe) testing a F S intervention, including training for service providers, one-on-one coaching, and access to no-cost savings accounts for low-income people with serious mental illness (n=31), 45% of whom had a history of criminal justice involvement, and 75% of whom were Black or Latinx. Participants valued the support, with half attending coaching sessions regularly. They opened bank accounts, improved credit, paid more bills on time, paid more attention tofinances, set financial goals,spenttheirmoneymoreresponsiblyandlessimpulsively, felt less vulnerable to financial victimization, and felt more confident about managing money. There was no improvement in saving regularity, feeling debt burdened, financial stress or overall financial situation; barriers included lack of income, disability benefit asset limits, and lack of access to fee-free bank accounts. In a qualitative study, Harper explored perspectives of people with representative payee experience to identify existing and potential fintech tools useful for this population, and recommended ways that banks and credit unions can better accommodate people with mental health challenges; these recommendations were presented to local financial institutions in a White Paper prepared in collaboration with the Yale Law school. Harper was PI of a mixed methods study exploring the experiences of debt and financial hardship among recently incarcerated people using mental health services and their social network members (n=41), 62% of whom were Black or mixed race, and 13% Latinx. The study found that incarceration deepens existing problem debt and adds new debts from in-prison costs and identity theft which complicate the search for housing, employment, and financial stability, leading to further debt, stressing social relationships, and reproducing social and economic inequality. Harper conducted a scoping review of research on incarceration and debt, with similar findings. Harper has also led studies exploring debt among people with serious mental illness, and

recently incarcerated people with chronic health problems, finding that Black and Latinx people are more likely to have debt, number of debts is associated with depression, financial stress and poor health and people with serious mental illness who have debt are more likely to skip appointments for mental or physical healthcare. Harper is currently PI of a mixed methods community Based Participatory Research (CBPR) study exploring associations between debt and health of low-income people (n=402) in New Haven, the site of this study, including 66% Black or Latinx, 28% people with incarceration histories, and 20% people who self-identified as having a disability. Pertinent initial findings from this study are that people who are Black or Latinx have more debts than others, and that people with more debts are more likely to report mental or physical health challenges. In addition, Harper has been involved in training relevant to this project, including: i) training social service providers using the Your Money Your Goals curriculum, giving them skills to address client financial difficulties; ii) training people providing services to justice-involved people in New Haven using the same curriculum and the companion-guide focused on justice-involved people; iii) training mental health providers using the same curriculum and the companion- guide focused on people with disabilities. She is currently o-I of a Veterans Administration project, providing recovery-oriented money management training and consultation to agencies serving homeless veterans.

Our team has led research showing strong evidence of the value of peer support as a bridge between social inequities and optimal health. Our team has been on the forefront of developing and evaluating peer interventions since the 1990s, demonstrating that those who have "been there" can serve as powerful motivators, role models, and educators for others. Peers can effectively engage people who have been otherwise difficult to engage, connect them to needed services, while instilling hope, and promoting activation and self-care. In our research, peer interventions have been associated with moderate to large effect size improvements among persons with serious mental illness in: hope, sense of well-being, self-care, and quality of life; drug and alcohol use and hospitalizations; and community tenure after hospitalization. Meta-analyses and systematic review show that peer-delivered services are generally equivalent to usual care conditions for adults with SMI in regard to traditional clinical outcomes (e.g., symptom severity), and superior to usual care when examining more recovery-oriented outcomes (e.g., hope, empowerment, quality of life). Research by Dr Bellamy with Black and Latinx people with Substance-Use-Disorder (SUD) indicates that Imani, a peer support and community health worker (church facilitators) driven intervention can impact overall wellness (the 8 dimensions of

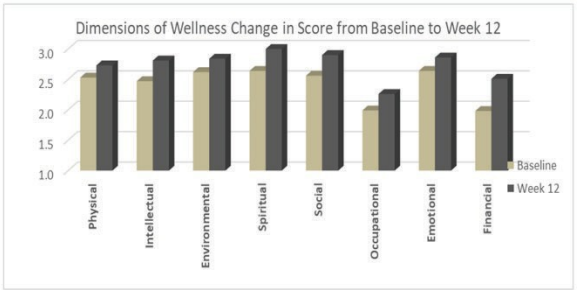

Figure 1: Results of Imani project

wellness), including improvements in financial health from baseline to 12 weeks following the intervention (see figure 1). To date, over 1000 individuals have enrolled in the Imani program across the state of T; Imani participants across 7 sites were from diverse backgrounds and experiences: 43% female, 22% Latinx, and 61% Black. The majority had experienced incarceration (65%), and 14% were on probation parole. Data collected from cohorts 2 and 3, found 43% of those who began treatment were retained at weeks 12 and 32% were retained at week 22[181]. In addition, we found a significant increase in all 8 scores on the Dimensions of Wellness assessment from pre- treatment to week 12 (time $p < .05$). This work indicates that peers can be effective in working with people to address SDOH and other experiences resulting from structural discrimination.

***Our team has conducted research on peers for justice-involved people with mental illness*:** Dr Bellamy's work has also focused specially on the training, development, and implementation of Forensic Peer Support (FPS) services. People with histories of mental health and SUD challenges returning to the community after incarceration face tremendous challenges in successful reentry to community, including reconnecting or connecting with mental health and substance abuse treatment, finding adequate housing, finding employment, reuniting with family and friends, dealing with finances, etc. Recidivism remains high principally because of these challenges. FPS can help people connect with their communities, access treatment and other supports, and assist with psychological, social, and financial challenges, and in so-doing can reduce recidivism substantially. Peer support may help with confidence and self-esteem when dealing with financial challenges. In previous research conducted by Dr Bellamy and colleagues on the PeerStar forensic peer project for people with mental health and SUD challenges returning from jails in rural Pennsylvania, all had a mental illness diagnosis. Surprisingly, in the first year after release from prison, participants did much better than those in the general US prison population in terms of re-incarceration rates (21.7 percent vs 43.4 percent). While preliminary findings of this approach, this study reaffirms the idea that forensic peer support can help reduce recidivism rates for people diagnosed with a mental illness coming out of prison.

Legal, policy and cultural barriers impacting financial capability for justice-involved people with mental illness: One-on-one interventions alone cannot address financial difficulties and related health problems. Effective financial capability programs partner with banks and credit unions to ensure people have access to needed financial products, which can entail encouraging those financial institutions to change their operational policies. Effective financial capability programs also acknowledge and partner to address the broader structural conditions that cause financial difficulties through supporting community efforts for legal and policy reform. The financial difficulties that we seek to address are rooted in specific community and societal level policy decisions. Structural discrimination operates through these financial difficulties, with populations that have been marginalized, including people with mental illness, most negatively impacted. People who are justice involved are affected by policies including fines and fees, bail and legal counsel, and cost of in-prison amenities.

In Connecticut, the site of this project, people who have been incarcerated are indebted to the state though a lien, which can claim up to half of the value of a person's estate, inheritance, lawsuit proceeds, or lottery winnings, up to 20 years after their release, as payment for the cost of incarceration. People in transitional housing are not eligible for the Earned Income Tax Credit (EITC), which has been shown to improve health of recipients[25]. All of these barriers can be addressed through legislative, regulatory, and organizational policy reform. Recently, community-based campaigns in Connecticut changed laws regarding the cost of prison phone calls, and regarding a lien on welfare recipients, similar to the incarceration lien mentioned above.

2 Rationale/Significance

2.1 Rationale and Study Significance

This project will test a community level intervention to address financial difficulties of people who are justice-involved, low-income and have mental health challenges, in a setting where this population is disproportionately Black and Latinx. The study will assess whether training service providers and staff of financial institutions and supporting community collaborations results in greater availability of community level services, reduced local structural discrimination and increased community resources. An individual component of the intervention will involve a randomized control trial of participants receiving F S with participants randomized to receiving additional peer support or not. The mixed-methods assessment will include validated quantitative measures, qualitative interviews, focus groups, and participant observation. Integration of data sources across quantitative or qualitative measures will allow for a contextualized understanding of the impact of the recovery Finance intervention on community level determinants of health. BP methods will be employed throughout the research to provide ongoing feedback about research design and implementation, study results, and interpretation. Our study timeline is included in the PHSform.

CBPRITransformative paradigm: The root causes of the target group's financial difficulties are understood as forms of structural violence, referring to the ways that social, political, and economic systems harm some more than others. Intervention at the systems level is needed to effect individual change. In addition to racism, poverty and discrimination, the financial marginalization of the target group, exacerbated by incarceration, is a form of structural violence. To address this structural violence, our BP methods will be informed by a transformative paradigm of research, which pays particular attention to issues of power. In keeping with this paradigm, we use a cyclical mixed methods approach, involving community not only in defining the problem, developing research design, and participating in data collection and analysis, but also in considering future research needs, and "tying the data collected to social action".

Conceptual model and target population. Our conceptual model (fig.2) posits that people who are justice- involved and have mental illness, who are disproportionately Black and Latinx, suffer from structural violence associated with poverty, discrimination, racism, including being excluded from financial services, and dealing

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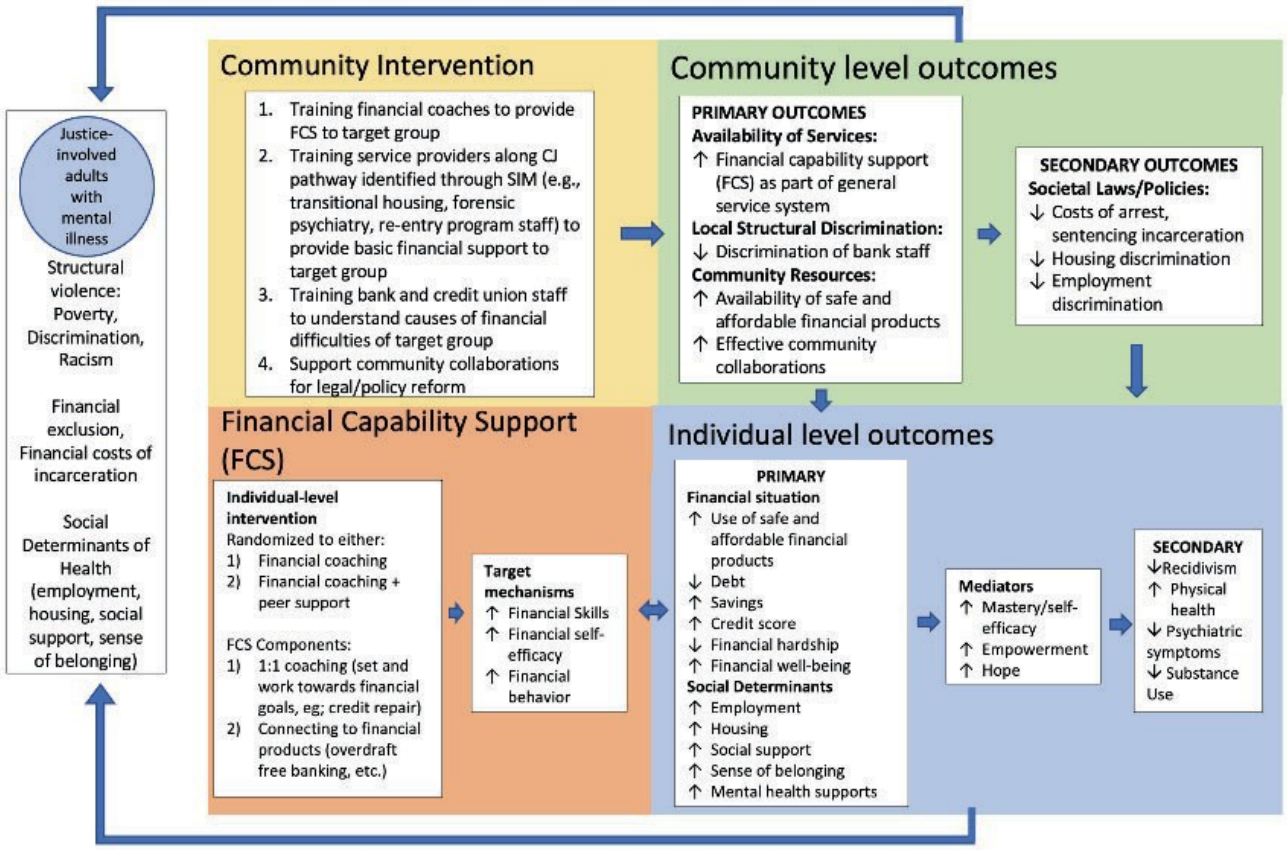


Figure 2: Conceptual Model for Recovery Finance

Conceptual model and target population. Our conceptual model (fig.2) posits that people who are justice- involved and have mental illness, who are disproportionately Black and Latinx, suffer from structural violence associated with poverty, discrimination, racism, including being excluded from financial services, and dealing with the financial costs of incarceration, as well as associated social determinants of health. This project will intervene at the community level through a continuous BP process, involving regular community meetings and consultation.

Community societal level: Activities at the community level will include: i) Training financial coaches to provide F S to the target group; ii) Training people who provide services along the criminal justice pathway to include basic financial support as part of their ongoing work with the target group; iii) Training bank and credit union staff to understand the causes of the target group's financial difficulties, and how access to financial services can help to address those difficulties, and; iv) Supporting

community collaborations to address legislative and regulatory policy reform. We hypothesize that these community level interventions will result in changes in community determinants, including greater availability of services (F S integrated into service system), reduced local structural discrimination (less discrimination among financial institution staff), and more community resources (greater availability of safe and affordable financial products, more effective community collaborations). We also hypothesize that more effective community collaborations will impact societal level outcomes through influencing policies and laws, but most likely these changes will not have a measurable impact on financial well-being and distal outcomes during the project period.

Individual level: As a result of changes in community determinants, we hypothesize that the target group will have greater access to F S services that will improve their financial situations and financial well-being through identified target mechanisms (financial skills, financial self-efficacy, and financial behavior). Less discrimination among financial institution staff and more availability of safe and affordable financial products will directly affect financial situations and financial well-being. Improved financial well-being will directly affect physical health, psychiatric symptoms, substance use and recidivism, medicated by mastery self-efficacy, empowerment, and hope.

Improved financial well-being will also impact health and recidivism indirectly through its effect on employment, housing, social support outcomes, as well as a sense of belonging, all of which affect health and recidivism.

We also hypothesize that improved financial well-being will impact health directly through identified target mechanisms. We hypothesize the F S intervention plus or minus peer support increases primary outcomes through the target mechanisms of increased financial skills, financial self-efficacy, and financial behavior.

2.2 Risks

1) Service providers/bank and credit union staff: Focus group participants might also experience distress when talking about their training experiences. The focus group facilitators are experienced and trained to address such situations. In our experience with focus groups, there has never been an unmanageable situation of distress experienced by a focus group participant.
2) Potential risks to study participants may include distress by participating in an interview about their lives or discussing their financial health with financial coaches and Peer Wellness coaches. This sharing may evoke an array of responses, including emotional, psychological, cultural, or racial distress for some participants by recalling difficult experiences in their own life. The Financial and Peer Wellness coaches are trained and can assist the individuals in processing these emotions. The Research Assistant staff who will conduct interviews are also trained to address these situations. In our experience, such events are very unlikely. If it is the case that a participant would like to talk further about their difficult experience and need further support, they will be offered resources such as local hotlines, community

based acute mental health service affiliate organizations in New Haven, (e.g., the Yale Department of Psychiatry), in addition to Dr. Elizabeth Flanagan who is a licensed clinical psychologist on our research team, and the research team's contact information. These resources will be made accessible with each of the Financial and Wellness coaches, and members of our research team.

3) A breach of confidentiality is possible, but not likely for all study participants. Should a breach be noted, the participant will be informed immediately, along with the APIs, and reported to the IRB for review and further direction.

4) The risk level to participants in this study is minimal and the likely impact is low.

We believe, based on our experience, current safeguards, and additional safeguards to be put in place as part of this study, that we will be able to avoid violations of confidentiality or risk of possible distress to research participants. The importance of the knowledge expected to result from this study to our target group and to communities and society are substantial and make the risk to subjects reasonable.

2.3 Anticipated Benefits

(1) Service providers/bank and credit union staff: We anticipate that research participants will benefit by contributing to the ability of their organizations to better address the financial difficulties of people with incarceration histories and mental health challenges.

(2) Individuals with incarceration histories and mental health challenges: We anticipate that research participants will benefit by improving their financial, physical, and mental wellness through the intervention. This will further contribute to the field of social and criminal justice, mental health, and minority health and health disparities science by providing the data necessary to further our understanding of evidence-based culturally informed treatment options, but more importantly, provide an opportunity to impact the individual lives of minoritized people with history of incarceration and mental health challenges, systemically.

The risks associated with this study are minimal and we have a reasonable plan for addressing any unforeseen events. The potential benefits of this study to our study population and to communities and society are substantial. Therefore, we think the potential benefits to participants significantly outweigh the risks.

This proposed study has the potential to enhance our scientific knowledge of considerable significance in understanding strategies to increase access to evidenced-based treatments and culturally responsive financial health and wellness health for people coming out of prison with mental health challenges. We are attempting to understand how to reduce financial difficulties faced by justice-involved individuals with mental health challenges returning to their communities after incarceration. We hypothesize that the

intervention will affect community-level health determinants including: i) more availability of services (integrating financial capability support into the existing service environment); ii) less local structural discrimination (by bank staff against justice-involved people who have mental illness); iii) more community resources (access to safe, affordable financial products, effective community collaborations working towards legal/policy reform). Resulting individual level outcomes will include improved financial well-being, which will improve recidivism and health outcomes directly, and indirectly through improving employment and housing outcomes, increasing sense of belonging, and strengthening social network and mental health supports.

3 Study Purpose and Objectives

3.1 Purpose

This proposal will address financial wellbeing, an often overlooked but important factor impacting reentry for justice-involved people with mental health challenges, who are disproportionately Black and Latinx. The project will change community level determinants by integrating financial capability support (one-on-one coaching and access to financial tools and services) into existing services and training bank and credit union staff to reduce discrimination. It will also support collaborative community efforts working towards upstream policy and legal reforms to reduce the incidence of those financial challenges.

3.2 Hypothesis

We hypothesize that these community level interventions will result in changes in community determinants, including greater availability of services (FCS integrated into service system), reduced local structural discrimination (less discrimination among financial institution staff), and more community resources (greater availability of safe and affordable financial products, more effective community collaborations). We also hypothesize that more effective community collaborations will impact societal level outcomes through influencing policies and laws, but most likely these changes will not have a measurable impact on financial well-being and
distal outcomes during the project period. Individual level: As a result of changes in community determinants, we hypothesize that the target group will have greater access to FCS services that will improve their financial situations and financial well-being through identified target mechanisms (financial skills, financial self-efficacy, and financial behavior). Less discrimination among financial institution staff and more availability of safe and affordable financial products will directly affect financial situations and financial well-being. Improved financial well-being will directly affect physical health, psychiatric symptoms, substance use and recidivism, medicated by mastery/self-efficacy, empowerment, and hope. Improved financial well-being will also impact health and recidivism indirectly through its effect on employment, housing, social support outcomes, as well as a sense of belonging, all of which affect health and recidivism. We also hypothesize that improved financial well-being will impact health directly through identified target mechanisms. We hypothesize the FCS intervention plus or minus peer support increases primary outcomes through the target mechanisms of increased financial skills, financial self-efficacy, and financial behavior.

3.3 Objectives

This research project will use Community Based Participatory Research (CBPR) methods to achieve the following specific aim:

1) Change community level determinants that impact financial well-being and health of the target group by training existing service provider including: i) community-based financial capability providers to be able to address financial difficulties of the target group; ii) service providers along the criminal justice pathway to be able to provide basic financial guidance to target group; iii) financial institution staff to reduce discrimination related to financial consequences of justice-involvement and mental illness. We will also support community collaborations working for legal/policy reform that impacts finances of target group.

2) Use mixed methods to assess impact on community determinants, measuring integration of financial capability support into existing services, ability of financial coaches to support target group, access to financial products, attitudes, knowledge and behavior of bank staff, strength of community collaborations, and progress towards changes in laws and policies.

3) We will assess impact on individuals by measuring target mechanisms (financial skills, self-efficacy and behavior) hypothesized to mediate the relationship between financial capability support and primary outcomes including financial well-being and other health determinants (employment, housing, social support, mental health supports, and belonging), secondary outcomes (health and recidivism) and mediators between primary and secondary outcomes (hope, empowerment, and mastery).

4) Assess the value of integrating peer support into community-based financial capability support for the target group by randomizing participants into two groups, financial capability support only, or financial capability support plus peer support.

4 Study Design

Phase I Year 1:

Following notice of award, we will convene the Community Advisory Board (CAB) and research team to review protocol and finalize preparations. The CAB will meet quarterly. We will also identify a broader stakeholder group to participate in refining the study design, and help with recruitment, in addition to assessing progress towards community level outcomes. We will support this stakeholder group to convene at least once annually and will also hold annual public community conversations. The stakeholder group will include people with lived experience, family and other social network members, and service providers, including financial institutions. We will work with our partner, AHS, to identify an NH-FE employee who will lead in developing referral pathways for the target group, providing direct coaching to interested individuals and supporting other coaches as needed.

Sequential Intercept Mapping to identify intervention points:

The Sequential Intercept Mapping (SIM) model identifies 'intercept points' at which to intervene to help people with behavioral health challenges who are justice involved and try to divert them from the system. In SIM workshops stakeholders and service providers use the model to collaboratively identify the resources that exist at each intercept, and the gaps in support and services. We will adapt the SIM method to identify where financial difficulties arise as a person moves through the criminal justice system and refine training materials for service providers working across the system to help them address those difficulties early on, for example by helping people freeze credit, defer student loans, and suspend child support payments.

Co-design workshops:

Building on the SIM results, we will organize a follow-up co-design workshop at which the same group will collaboratively finalize the design of the project, including identifying appropriate staff to target for training, and refining the content of that training. We will build on existing training materials including the Consumer Financial Protection Bureau (CFPB) Your Money Your Goals focus on reentry Disabilities toolkits, for which Dr. Harper is a trained instructor, Dr. Harper's guide to managing incarceration-related debt, and a credit repair toolkit designed for justice-involved people. The research team has experience conducting both SIM and co-design workshops about similar issues.

Finalize and implement service provider training:

After collectively finalizing training materials we will train two groups of people; a) existing coaches working for the New Haven Financial Empowerment Center (NHFEC) to enable them to address the financial difficulties faced by the target group, and b)service providers currently working with the target population at various points along the criminal justice trajectory, including staff of jail diversion and forensic psychiatry programs, pre-sentencing programs, public defenders, in-prison counselors, probation and parole officers, and staff of transitional housing and reentry programs, to enable them to address common financial

problems that people may face, and to understand when a referral to financial coaching is possible/appropriate; c) bank and credit union staff to understand the causes of the financial difficulties faced by the target group, and how access to financial services can help to address those difficulties. We will educate staff of financial institutions and regulators, including the State Department of Banking and the local FDI representative, about the structural roots of the financial challenges faced by people who have been incarcerated, to reduce existing discrimination. To accomplish this, we will partner with BankOnConnecticut, an existing coalition of banks and regulators, for which PI Harper is a steering committee member*;* All trainings will be offered twice more annually in case of staff turnover. Each training will be repeated twice more, in years 2 and 3, to provide refresher training to people already trained, and to train any interested newly hired service providers/staff. Following the training, we will conduct a series of three **annual focus groups** with people who participated in each of the above trainings (**N=60).**

Phase II:

Ongoing support for trained service providers:

Service providers who engage with people through the criminal-justice pathway and who have been given financial capability training will be invited to participate in twice-yearly check-in meetings with NH-FE financial coaches, to discuss their experiences using the skills learned from the training and the guidance materials, and to collectively address any challenges faced.

Ongoing support for community collaborations:

Through the BP process, we will support community collaborations working on relevant legal and policy reform, including preparing policy briefs to share relevant findings from our work, such as the health impact of FCS. We do not seek to influence the direction of any associated advocacy or to organize any lobbying activities. The laws and policies that may be impacted will depend on collective determinations made by involved stakeholders, and on changing political circumstances.

FCS for people recently released from jail who have mental health challenges:

Eligible individuals - people over 18 years old, with a self-reported history of mental health challenges, released from prison within the last 24 months, living or using services in the City of New Haven, and interested in receiving financial guidance - will be recruited from transitional housing facilities, a local reentry welcome center, and a mental health clinic providing services to justice-involved adults and invited to enroll in our study of **FCS** at the NH-FE . **FCS** comprises a) one-on-one financial coaching, which entails at-least monthly meetings with a financial coach. Initial meetings are in person; subsequent meetings can be via zoom, phone or in person; b) support with opening an overdraft-free account. Coaches can also help people access other financial products such as free tax preparation (VITA), credit builder loans, or online bank accounts, or products recommended by our Justice Tech partner.

Peer support:

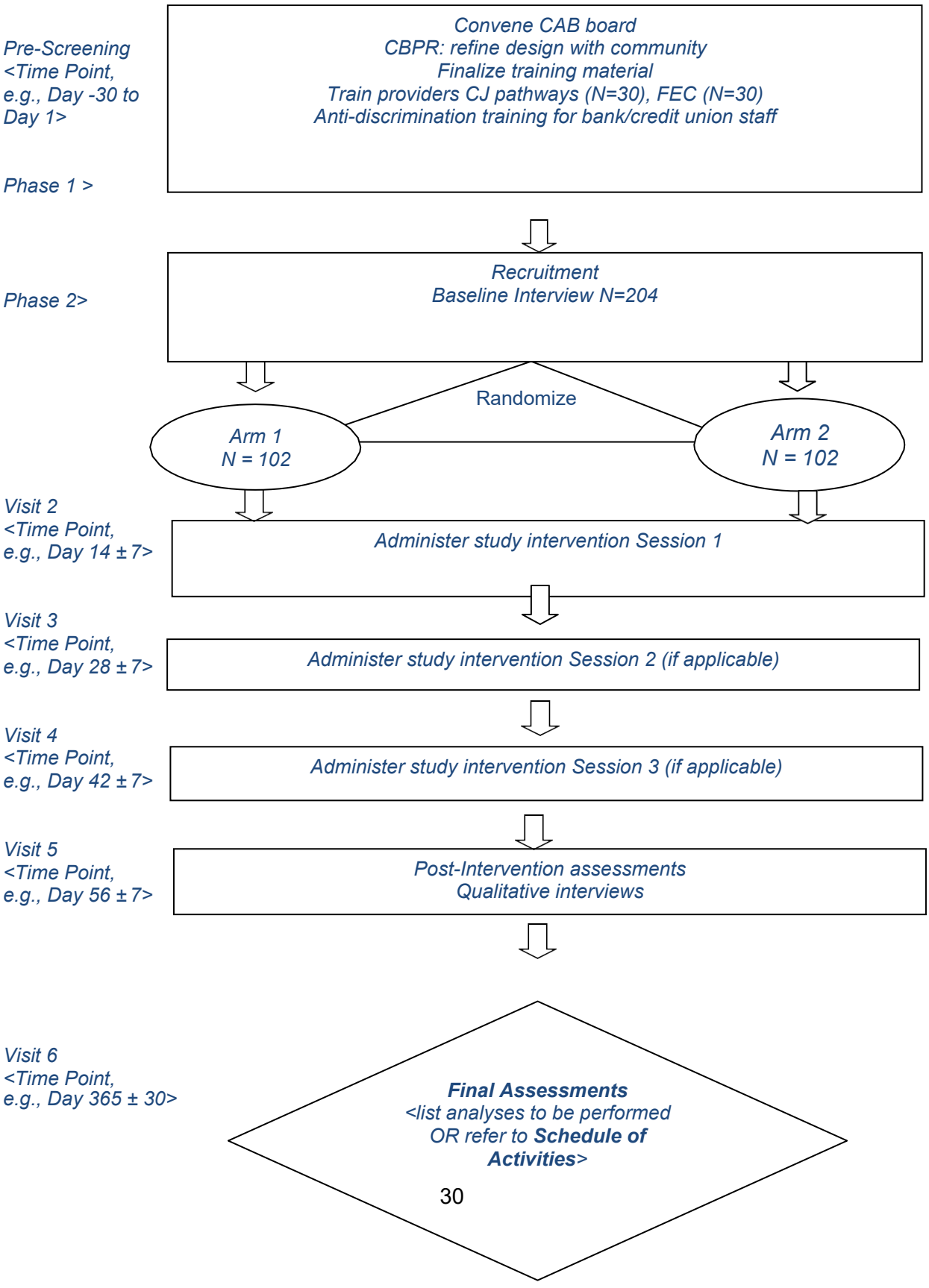
Half of our sample, stratified by gender, will be randomized to the 'treatment plus' group, and will also be offered one-on-one peer support from a trained Recovery Support Specialist. The peer supporter will be trained in forensic peer support and the 8 dimensions of wellness to give them additional skills to assist participants in addressing SDOH challenges. Dr. Bellamy and peer supporters on this project have served as trainers in forensic peer support, wellness coaching around the 8 dimensions, and on peer support training and certification. These training technologies are used throughout the country in providing training to peer supporters.

Individuals with Incarceration Histories and Mental Health Challenges:

This research study will enroll 204 people **(N=204)** who have been released from jail or prison **24 months ago or less** and who have mental health challenges. Participants will be randomized in two arms – (N=102 participants in each arm). They will be enrolled on a continuous basis starting in month 9 of year 1 until month 4 of year 3. We plan to enroll 36 participants in year one, 118 participants in year two, and 50 participants in year 3. All participants will be enrolled in New Haven, CT county. The Peer Wellness Coaches and other research staff members have established long-term trusting relationships with people in the New Haven community, which will enhance our recruitment efforts. Additional recruitment methods include flyers, word of mouth, local media advertisement resources, and social media. Mental Health and carceral services such as the Connecticut Mental Health Center (CMHC), halfway houses, community supervision programs, and the New Haven Re-entry Center will also be approached for the recruitment advertisement. If interested, the potential participant will contact the research assistant, and the researcher will answer any questions or concerns of the potential participant. If/when they decide to participate in the study, the potential participant will be screened for eligibility. The interested individual will answer screening to determine eligibility. If eligible and still interested, the participant will be invited for an interview for consent and baseline interview. Participants will be screened, consented, and complete their baseline assessments, after which they will be referred to a meeting with the New Haven Financial Empowerment Center (NH-FEC) &CAHS) financial coach, within 30-days of their baseline assessment.

Participants will be randomized to two arms: Arm #1 financial capability support = a) one-on-one financial coaching, which entails monthly or more frequent meetings with a financial coach; initial meetings are in person, and subsequent meetings can be via zoom, phone or in person, depending on the convenience for the client and b) access to safe and affordable financial services, which includes support with managing any existing bank accounts, or supporting a person to open a new overdraft-free account. Coaches can also help people to access other financial products such as free tax preparation (VITA), credit builder loans, online bank accounts, or other products recommended by our Justice Tech partner.

Arm #2 with peer support = in addition to financial capability support will also be offered one-on-one peer support from a trained Recovery Support Specialist…during the period they are receiving the intervention. Wellness coaches will provide weekly meetings (30 to 60 minutes duration).


Pre-Screening
<Time Point,
e.g., Day -30 to
Day 1>
Convene CAB board
CBPR: refine design with community
Finalize training material
Train providers CJ pathways (N=30), FEC (N=30)
Anti-discrimination training for bank/credit union staff
Phase 1 >
Phase 2>
Recruitment
Baseline Interview N=204
Randomize
Arm 1
N = 102
Arm 2
N = 102
Visit 2
<Time Point,
e.g., Day 14 ± 7>
Administer study intervention Session 1
Visit 3
<Time Point,
e.g., Day 28 ± 7>
Administer study intervention Session 2 (if applicable)
Visit 4
<Time Point,
e.g., Day 42 ± 7>
Administer study intervention Session 3 (if applicable)
Visit 5
<Time Point,
e.g., Day 56 ± 7>
Post-Intervention assessments
Qualitative interviews
Visit 6
<Time Point,
e.g., Day 365 ± 30>
Final Assessments
<list analyses to be performed
OR refer to Schedule of
Activities>

4.1 Study Duration

The research study duration is planned four years after IRB approval, 8/31/2026.

4.2 Outcome Variables/Endpoints

Outcomes and measures. We have identified measures and sources of data for each element in our conceptual model and have mechanisms in place to collect the data at key points throughout the study.

Community outcomes and measures: *i) FCS built into services system:* We will count number of people trained, number of people fitting description of target group accessing services at the NH-FE , asking about the issue atannual focus groups with service providers, at quarterly AB meetings and annual stakeholder and community meetings. *ii) Reduced discrimination among bank staff regarding mental illness and criminal justice involvement.*We will count number of people trained, ask at annual focus groups with bank and credit union leaders staff if they have noticed different attitudes towards and treatment of target group, and ask at quarterly AB meetings and annual stakeholder and community meetings if they have noticed different attitudes towards and treatmentof target group; *iii) More financial products that meet needs of formerly incarcerated people with mental illness.*We will track product offerings through visiting calling branches, ask about products at annual focus groups withbank and credit union leaders staff, and ask at quarterly AB meetings and annual stakeholder and community meetings whether people have noticed improved product offerings; *iv) More community collaborations.* We will document community collaborations and partnerships working towards policy and legal reform created as a result of the project and monitor and document the activities of those partnerships. Due to a lack of a randomized trialfor the community level interventions, we plan to conduct a pre-post analysis, e.g., use a pair analysis to determine if there are differences between baseline (pre-intervention) and during follow-up (post-intervention). We will also consider the use of segmented regression, separating the time periods into segments based on keyevents happening (i.e., trainings offered) and analyze changes over time. For outcomes for which we are able to obtain "control" data (state level data on recidivism), we will employ a difference-in-difference approach to help ensure that the impact being observed can be attributed to the intervention and not just a temporal trend. **Societal outcomes and measures:** Any policy legal reforms resulting from the improved community collaborationsmay be beyond the scope of this grant, given the time such changes take. We will document community meetingsand activities and will monitor the progress of any legal or policy reform.

Individual outcomes and measures: Based on statistical power analysis (described below), we will recruit up to 204 participants. Potential participants will be given study information, including a contact number. On calling, they will be screened for eligibility, and given study information. If they are interested in participating, a meeting will be arranged at which, after obtaining written informed consent, they will be administered the baseline interview packet and paid $50 for completing the interview. They will then be referred to the NH-FE for FS support peer support. Participants will also complete the interview measure packet at 6-month and 12-month follow-up. Financial situation (see measures below) will,for people engaged in F S, be measured using the NH-FE existing data monitoring system, Financial Empowerment enter Boost Outcome Tool (FE BOT), which we have permission to access for study participants. ***Qualitative component****:* A sub-sample of 18 participants, selected randomly, will be invited to participate in in-depth qualitative interviews at baseline, 6- month, and 12-months. Interview guides will be developed to probe specific issues identified through community and AB meetings; the content of this guide may change over time based on the results of ongoing quantitative and qualitative data collection, and in discussion with the AB. Interviews will last between 45 minutes to 1 hour,and participants will be paid $50. All in-depth interviews will be audio-recorded and transcribed. ***Participant Observation***. We will add context to our understanding of the interview data through adapted participant observation methods. We will use tools adapted from ethnographic methods, such as focused ethnography and apid-Assessment Ethnography to obtain 'thick description. For example, we will spend time with participants before and after coaching sessions and will take detailed, reflexive notes, though we will not participate in coaching sessions. We will spend time in spaces and institutions pertinent to the financial lives of our target group, identified through meetings with the advisory board and the BP process, and take detailed field notes.

4.2.1 Primary Outcome Variables/Endpoints

Primary outcomes: Target mechanisms to be measured include financial skills, financial self- efficacy, and financial behavior. Primary outcomes include financial situation (use of financial products, income, current debt, savings, credit score, financial hardship), financial well-being, employment, housing, social support, sense of belonging, and mental health supports.

Financial capability support (FCS) as part of general service system:

We will measure this outcome by counting number of people trained, number of people fitting description of target group accessing services at the NH-FEC, asking about the issue at annual focus groups with service providers, and at quarterly CAB meetings and annual stakeholder and community meetings.

Discrimination of bank staff:

We will measure this outcome through counting number of people trained, asking at annual focus groups with bank and credit union leaders/staff if they have noticed different attitudes towards and treatment of target group, and asking at quarterly CAB meetings and annual stakeholder and community meetings if they have noticed different attitudes towards and treatment of target group.

Access to safe and affordable financial products:

Indicated by:

Greater availability of existing products and introduction of new products

Measured by (quantitative):

- Track product offerings at local banks/credit unions though observation and call to local branch managers (annual years 1-4)

Measured by (qualitative):

- Focus group with bank and credit union leaders (annually years 1-4, representatives of approx. 10-15 institutions)
- CAB/CBPR meeting notes (ongoing - CBPR community/stakeholder meetings will be held at least annually. CAB meetings will be held quarterly).

Effective community collaboration:

Indicated by:

Partnerships created, meetings held, bills supported Measured by (qualitative):

- Research team meeting notes (ongoing)
- CAB/CBPR meeting notes (ongoing - CBPR community/stakeholder meetings will be held at least annually. CAB meetings will be held quarterly)
- Media tracking.

Use of safe and affordable financial products:

From Administrative data from the Financial Empowerment Center Boost Outcome Tool (FECBOT) and by self-report (do you currently have a bank account? Does your account allow for charging of overdraft fees?).

Debt:

From Administrative data from the Financial Empowerment Center Boost Outcome Tool (FECBOT), self-report (please list all the debts you currently owe)and as part of a validated measure of financial hardship.

Credit score:

From Administrative data from the Financial Empowerment Center Boost Outcome Tool (FECBOT) and by self-report (what is your current credit score - select from range).

Income:

From Administrative data from the Financial Empowerment Center Boost Outcome Tool (FECBOT) and in the Lehman (1988) Quality of Life interview

Financial well-being:

1) A validated measure of financial stress, the Incharge Financial Distress/Financial Well-being Scale (IFDFW) Scale

(Prawitz 2006)

2) A validated financial well-being measure which assesses a person's feelings about aspects of their financial situation (CFPB 2017)

Employment:

We will measure employment as well as satisfaction with employment with the Lehman (1988) Quality of Life interview, which has established reliability and validity.

Housing:

We will measure housing as well as satisfaction with living situation with the Lehman (1988) Quality of Life interview, which has established reliability and validity.

Social support:

We will measure social support using the ISEL-12 scale. This 12-item scale has established reliabilty and validity.

Mental health supports:

In our self-reported Service Use measure, participants will be asked about the number of visits for outpatient mental health services, self-help groups, peer support, social rehabilitation, and supported employment.

4.2.2 Secondary and Exploratory Outcome Variables/Endpoints (if applicable)

Secondary outcomes: These include physical health, psychiatric symptoms, substance use and recidivism, with mediators including mastery self-efficacy, empowerment and hope.

Recidivism:

Recidivism will be assessed through the public access criminal database called ctlookup.org

Physical health:

Physical health will be measure by the SF-12. The SF-12 has good internal consistency (Cronbach alpha coefficients of 0.72 to 0.89); test retest reliability (r = 0.73-0.86).

Psychiatric symptoms:

The 9-item PHQ-9 will measure depression. Reliability and validity of the tool have indicated it has sound psychometric properties. The Beck Anxiety Inventory will be used to assess Anxiety.

Wellness:

Overall Wellness will be measured by the 8 Dimensions of Wellness Measure which assesses physical, environmental, spiritual, social, emotional, financial, occupational, and intellectual wellness (Swarbrick 2012).Wellness goals for each of the 8 dimensions, activities engaged in, and an self-assessment of where participants are currently and where they would like to be with respect to each of the 8 dimensions will be also logged in the coaching measure at peer coaching sessions.

5 Study Participants

5.1 Study Population

- At least thirty **(N=30)** financial coaches and criminal justice service providers from the New Haven area will participate in training activities during the project's first year as part of our partnership with the NH-FEC and local organizations providing services to the target group. The training will be repeated twice more, in years 2 and 3, to provide refresher training to people already trained, and to train any interested newly hired service providers. At the end of years 1, 2, and 3, people who received that training will be recruited to participate in an online focus group to discuss the intervention (3 focus groups over 3 years with 10 participants each) **(N=30).**
- At least ten **(N=10)** staff working for banks or credit unions in the New Haven area will also participate in training activities during the project's first year as part of our partnership with local banks and credit unions through the BankOn Connecticut Coalition (run by our partner organization, CAHS). The training will be repeated twice more, in years 2 and 3, to provide refresher training to people already trained, and to train any interested newly hired staff. At the start of years 2, 3, and 4, people who participated in the training for bank and credit union staff will be recruited for a focus group (3 focus groups over 3 years with 10 participants each) **(N=30).**
- This research study will enroll 204 people **(N=204)** who have been released from jail or prison 24 months ago or less and who have mental health challenges.

5.2 Number of Participants

At least thirty **(N=30)** financial coaches and criminal justice service providers from the New Haven area will participate in training activities during the project's first year as part of our partnership with the NH-FEC and local organizations providing services to the target group. The training will be repeated twice more, in years 2 and 3, to provide refresher training to people already trained, and to train any interested newly hired service providers. At the end of years 1, 2, and 3, people who received that training will be recruited to participate in an online focus group to discuss the intervention (3 focus groups over 3 years with 10 participants each) **(N=30).**

- At least ten **(N=10)** staff working for banks or credit unions in the New Haven area will also participate in training activities during the project's first year as part of our partnership with local banks and credit unions through the BankOn Connecticut Coalition (run by our partner organization, CAHS). The training will be repeated twice more, in years 2 and 3, to provide refresher training to people already trained, and to train any interested newly hired staff.
- At the start of years 2, 3, and 4, people who participated in the training for bank and credit union staff will be recruited for a focus group (3 focus groups over 3 years with 10 participants each) **(N=30).**This research study will enroll 204 people **(N=204)** who have been released from jail or prison 24 months ago or less and who have mental health challenges

5.3 Eligibility Criteria

- Participants must be 1) at least 18 years of age; 2) have been released from jail or prison 24 months ago or less; 3) self-identify as having mental health challenges; 4) living or using services in the City of New Haven and 5) be interested in receiving financial guidance.
- Ineligibility Criteria for the Financial Health and Mental Health after Incarceration intervention: Persons 1) less than 18 years of age; 2) not have been released from jail or prison 24 months ago or less; 3) not self-identify as having mental health challenges; 4) living or using services in the City of New Haven and 5) be interested in receiving financial guidance.
- Service providers/bank and credit union staff participant must be 1) at least 18 years of age and 2). a financial coach or criminal justice service providerfrom the New Haven area will participate in training activities during the project's first year as part of our partnership with the NH-FEC and local organizations providing services to the target group. The financial coaches and criminal justice service providers are neither participants nor research staff. These are community service providers. They are providing their usual services available to anyone.

5.4 Recruitment Procedures

Focus groups with trained service providers: Providers will be contacted using contact information shared during the training and asked if they are interested to participate in the focus group. Those who are interested will receive a Zoom link for the focus group. Prior to beginning the focus group, all participants will receive information about the study and the focus group, will have any questions answered, and will give verbal consent to participate.

At least ten staff working for banks or credit unions in the New Haven area will also participate in training activities during the first phase of the project, as part of our partnership with local banks and credit unions through the BankOn Connecticut Coalition (run by our partner organization, CAHS). At the start of years 2, 3 and 4, people who participated in that training will be recruited for a focus group (3 focus groups over 3 years with 5-8 participants each). Similar procedures utilized for the financial coaches and criminal justice providers focus groups will be utilized.

Individuals with incarceration histories and mental health challenges:
All participants will be enrolled in New Haven, CT county. The Peer Wellness Coaches and other research staff members have established long-term trusting relationships

with people in the New Haven community, which will enhance our recruitment efforts. Additional recruitment methods include flyers, word of mouth, and local media advertisement resources and social media. Mental Health and carceral services such as the Connecticut Mental Health Center (CMHC), halfway houses, community supervision programs, and the New Haven Reentry Center will also be approached for recruitment advertisement. If interested, the potential participant will contact the research assistant, and the researcher will answer any questions or concerns of the potential participant.

5.5 Consent/Assent Procedures/HIPAA Authorization

- Service providers/bank and credit union staff: Six focus groups will be conducted with trained financial coaches and criminal justice providers (3 focus groups with 10 participants each) and bank staff (3 focus groups with 10 participants each). These focus groups will be conducted after the end of training via an audio- video conferencing platform such as Zoom, approved by Yale University IRB. Participants are providers and will not receive compensation for their participation.
- Once a potential participant expresses interest in the proposed research study (by contacting the research team), the research assistant will give a detailed description of the study, describe what research activities are involved for the participant; review confidentiality and privacy, the risks and benefits of their participation, the importance of the knowledge gained, remind them that participation is voluntary and they may decline/opt-out of the study at any time, without consequence. The research assistant will answer any questions or concerns of the potential participant—if/when they decide to participate, the potential participant will be screened for eligibility. Interested participants will answer screening questions which include age; criminal justice involvement history, mental health history, and interest in receiving Financial Health coaching services. Participants will be screened, consented, and complete their baseline assessments within 30-days prior to their first appointment with the Financial Coach. If the potential participant meets eligibility criteria, they will be offered the option to complete the informed consent process 1) remotely using a smartphone 2) remotely using a tablet/personal computer, where a research assistant will be available to help the participant, or 3) in-person with a research assistant at a mutually agreed upon space in the community, or at Dr. Harper's PRCH research offices located in New Haven. Prospective participants choosing a remote option will receive instructions to access their assigned study link and unique personal identifier required for participation. Members of our research team will be available for those requiring any assistance (including literacy, both reading and technological).

- Online consent: The participant will read an informed consent form on the screen, which will provide a detailed description of the study, a description of the research activities, format, confidentiality and privacy, risks and benefits, voluntary participation, economic considerations, duration, and withdrawal. The form will clearly state that participants can withdraw participation at any time by closing the browser window, and that they may opt-out of any survey questions by selecting an alternative option (e.g., "I do not wish to answer this question"). *This will not affect payment or result in any consequences*. If the participant would like to consent for participation, they will do so by scrolling down on the consent form screen and actively indicating consent (e.g., click a button stating "I consent") if they agree to the terms of participation. The "I consent" button will indicate they understand their involvement in this online research study, and informed consent will be implied.
- In-person consent process: Research assistants will meet prospective participants at either 1) mutually agreed upon space in the community or (2) at Dr. Harper's PRCH research offices located in New Haven according to participant preference. The consent process will include all steps as described above, following established IRB approved procedures.
- Following informed consent, the participant will be asked to scroll to the next page to complete a demographic face sheet, then navigate through the online baseline measures by endorsing each item with their selected response (duration approximately 60 minutes). The participant will be able to see their progress by viewing a completion bar located on the survey page. Upon completion of the baseline assessment, the participant will be asked to enter their email address for verification of e-gift card to receive their payment for participation in the online study. The participant may also choose to receive their payment in the form of a physical gift card or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.
- For the 6-month assessments, participants will be offered an opportunity to update any demographic data on the face sheet and complete follow-up measures online by endorsing each item with their selected response (duration approximately 60 minutes). Upon completion of the 6-month assessments, the participant will be asked to enter their email address for verification of e-gift card payment for participation in the online study. The participant may also choose to receive their payment in the form of a physical gift card or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.
- For the 12-month assessments, participants will be offered an opportunity to update any demographic data on the face sheet and complete follow-up measures online by endorsing each item with their selected response (duration approximately 60 minutes). Upon completion of the 12-month assessment, the participant will be asked to enter their email address for verification of e-gift card payment for participation in the online study. The participant may also

choose to receive their payment in the form of a physical gift card or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.

- Qualitative interviews will be conducted with 20 consented randomly selected participants (duration approximately 60 minutes). These interviews will be conducted via an audio-video conferencing platform such as Zoom, approved by Yale University IRB or by telephone or in-person with digital-audio recording. The participant may also choose to receive their payment in the form of a physical gift card, or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.
- Participants will be given an opportunity to refuse digital audio-recording in the qualitative interview, but they will not be able to participate in the qualitative interview. They will be informed that all interviews are confidential.

6 Study Methods/Procedures

6.1 Study Procedures

The data collection for the research will be done via REDCap. Interested participants will provide informed consent electronically.

Following informed consent, the participant will be asked to scroll to the next page to complete a demographic face sheet, then navigate through the online baseline measures by endorsing each item with their selected response (duration approximately 60 minutes). The participant will be able to see their progress by viewing a completion bar located on the survey page. Upon completion of the baseline assessment, the participant will be asked to enter their email address for verification of $40 e-gift card to receive their payment for participation in the online study.

For the 6-month assessments, participants will be offered an opportunity to update any demographic data on the face sheet and complete follow-up measures online by endorsing each item with their selected response (duration approximately 60 minutes). Upon completion of the 6-month assessments, the participant will be asked to enter their email address for verification of e-gift card payment for participation in the online study. The participant may also choose to receive their payment in the form of a physical gift card or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.

For the 12-month assessments, participants will be offered an opportunity to update any demographic data on the face sheet and complete follow-up measures online by endorsing each item with their selected response (duration approximately 60 minutes). Upon completion of the 12-month assessment, the participant will be asked to enter their email address for verification of e-gift card payment for participation in the online study. The participant may also choose to receive their payment in the form of a physical gift card or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.

Qualitative interviews will be conducted with 20 consented randomly selected participants (duration approximately 60 minutes). These interviews will be conducted via an audio-video conferencing platform such as Zoom, approved by Yale University IRB or by telephone or in-person with digital-audio recording. The participant may also choose to receive their payment in the form of a physical gift card, or cash. Participants will receive a $40 e-gift card (or physical gift card or cash) for their participation.

Participants will be given an opportunity to refuse digital audio-recording in the qualitative interview, but they will not be able to participate in the qualitative interview. They will be informed that all interviews are confidential.

Economic Considerations:

- Participants will receive $40 cash, e-gift card, or gift card stipend payments for their participation in baseline, 6-month, and 12-month interview. (N=204 X $40 X3=$24,480)
- Participants will receive $40 cash, e-gift card, or gift card stipend payments for their participation in qualitative interviews. (N=20 X $40 X 2=$1600)
- Participants of the CAB will receive a $100 cash, e-gift card, or gift card stipend payment for their participation in CAB meetings (N=6 participants X $100 X 4 meetings per year X 4 years = $9600)
- Four community consultants will receive a $1000 stipend payment for their participation in community meetings (N=4 X $1000= $4000)

Visit Schedule Table

	Pre-screening (Pre-consent)	*Visit 1 Day 1*	*Visit 2 Day 14 ±7*	*Visit 3 Day 28 ±7*	*Visit 4 Day 42 ±7*	*Visit 5 Day 56 ±7*	*Visit 6 Day 365 ±30*	*Unscheduled Visit*
EMR Review Eligibility	*X*							

Informed Consent		X						
Demographics		X						
Clinical history		X					x	
Height & Weight		X	X				x	
Outcome Evaluation								
Pain Assessment (Brief Pain Inventory)		X			x		x	X
Quality of Life Questionnaire		X	X	x	x	X	x	
Randomization		X						
Control & Experimental Interventions – Occupational therapy		X	X	X	X			
Adverse Events Reporting		X	X	X	X	X	X	X

6.1.1 Data Collection

Data will be collected using the REDCap platform. Following informed consent, the participant will be asked to scroll to the next page to complete a demographic face sheet, then navigate through the online baseline measures by endorsing each item with their selected response (duration approximately 60 minutes). The measure packet will include a face sheet with demographic information, service utilization, SF-12V2, Quality of Life measure, ASI, ISEL-12, Adult State Hope Scale, Patient Activation Measure (PAM), Wellness in 8 Dimensions Inventory, Peer Support Service Satisfaction Survey, CMS_AHC HRSN, Patient Health Questionnaire (PHQ9), SCL-90 Anxiety Subscale, Peer Support Provider Contact Log, Community Connections Index, Empowerment Scale, Financial Distress and Financial Wellbeing Scale, Financial Hardship Strain, Financial Skill Scale, The Financial Self-Efficacy Scale, Money Mismanagement Client Rated Assessment. The participant will be able to see their progress by viewing a completion bar located on the survey page. Upon completion of the baseline assessment, the participant will be asked to enter their email address for verification of e-gift card to receive their payment for participation in the online study. The participant may also choose to receive their payment in the form of a physical gift card or cash. Participants will have the option to have these interviews administered by the research staff or on their own.

These interviews will be administered at baseline, 6-months, and 12 months.

Participants (N=20) will also offered participate in qualitative interviews, a recorded informal conversation regarding their experiences. Questions will be developed with the help of the stakeholders CAB and submitted to IRB for approval prior to implementation. The qualitative interviews will be digitally audio/video recorded. These interviews will take place at the end of the 6-month and 12-month assessments.

In addition to the quantitative and qualitative interviews, the researchers will also be collecting notes from the CAB meetings, stakeholder meetings, focus groups, and peer workers notes and contacts.

6.2 Method of Assignment/Randomization (if applicable)

Randomization will take place at the individual level. Participants will be randomized to treatment as usual (regular FCS) or treatment as usual with peer support using a 1:1 allocation ratio. The randomization scheme will be generated by the study statistician and given to the data manager for implementation using the Research Electronic Data Captures (REDCap's) randomization module to maintain allocation concealment. The randomization will be stratified by gender and carried out using random permuted block sizes of 2,4, and 6. Participants will be randomly allocated after completion of the baseline assessment.

6.3 Adverse Events Definition and Reporting

Dr. Harper (PI) is responsible for oversight of the DSMP and ensuring adherence to procedures for identifying, monitoring, and reporting potential adverse events (AEs) at each site. AEs will be monitored through frequent communication with recruitment sites and weekly team meetings. In accordance with NIH Reported Events policy, Dr. Harper will report all such events to the NIH Program Official and other monitoring entities (i.e., IRB, ISM). Non-serious adverse events, unrelated serious adverse events, unanticipated problems, and protocol violations will be reported annually in the NIH progress report and IRB continuation application and discussed at least quarterly with the ISM. Dr. Harper will also notify NIH, in writing, about: any suspension or termination of IRB approval (within 3 business days); deaths related to study participation (immediately and no later than 5 business days of learning of the death); unexpected Serious Adverse Events (SAE) related to study participation (within 10 business days of awareness of the SAE); and unanticipated problems involving risks to subjects or others (within 10 business days). Any serious or continuing noncompliance will be reported to the NIH PO by the Yale University IRB within 10 business days of determination.

As stated in the NIH Reported Events policy, all documentation will contain the following elements: “identifying information for the research protocol; the date on which the event occurred and the date at which the PI became aware of the event; a detailed description of the event and impact on the participant(s); a detailed description of the measures taken (including clinical) in response to the event (if any); confirmation that the appropriate monitoring entities and regulatory bodies have been notified as needed; and a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the event.”

6.4 Reaction Management

(1) Service providers/bank and credit union staff: Focus group participants might also experience distress when talking about their training experiences. The focus group facilitators are experienced and trained to address such situations. In our past experience with focus groups, there has never been an unmanageable situation of distress experienced by a focus group participant.
(2) Individuals with incarceration histories and mental health challenges: Potential risks to study participants may include distress by participating in an interview about their lives or discussing their financial health with financial coaches and Peer Wellness coaches. This sharing may evoke an array of responses, including emotional, psychological, cultural, or racial distress for some participants by recalling difficult experiences in their own life. The Financial and Peer Wellness coaches are trained and can assist the individuals in processing these emotions. The Research Assistant staff who will conduct interviews are also trained to address these situations. In our past experience, such events are very unlikely. If it is the case that a participant would like to talk further about their difficult

experience and need further support, they will be offered resources such as local hotlines, community based acute mental health service affiliate organizations in New Haven, (e.g., the Yale Department of Psychiatry), in addition to Dr. Elizabeth Flanagan who is a licensed clinical psychologist on our research team, and the research team's contact information. These resources will be made accessible with each of the Financial and Wellness coaches, and members of our research team.

6.5 Withdrawal Procedures

Participants who wish to withdraw from the research study may do so by informing the PI or research staff. This may be done verbally or in writing.

6.6 Locations/Facilities

- City of New Haven
- Connecticut Mental Health Center
- Yale University Program for Recovery and Community Health

7 Statistical Design

7.1 Sample Size Considerations

The primary outcome of interest is financial well-being. The primary hypothesis is that participants randomized to receive financial coaching plus peer support will have better financial well-being at 6-months compared to those who do not receive peer support. Based on prior research with low-income populations using financial well-being measures[106, 124, 208], we expect to be observed a standardized effect size of 0.5. With 90% power and a two-sided type I error rate of 0.05, using a two-sample t-test (conservative), we will need 86 participants per arm (172 total) to detect the 0.5 standardized effect size. To account for a 15% missing data rate at the 6-month time point, we plan to randomize 204 participants (102 per group). For secondary outcomes at 6- and 12-months (e.g., employment, sense of belonging, social support, housing), we hypothesize that those receiving financial coaching plus peer support will perform better. Based on an effective sample size of 172 (at 6-months) and assuming an additional 10% missing data at 12-months (n=154), assuming a two-sided type I error rate of 0.01 (conservative to account for multiple testing), we will have 80% power to detect standardized effect sizes 0.53 and 0.56 for 6- and 12-months, respectively, for continuous outcomes, and absolute differences ranging from 23%-26% and 25%-27% for

6- and 12-months, respectively, for binary outcomes, for baseline rates in the treatment as usual group ranging from 20%-50%.

7.2 Planned Analyses

Analysis: All analyses will be performed according to intent-to-treat with an overall type I error rate of 5% (two- sided) using SAS (ary, N) and (Project). All analyses will follow the design and account for stratificationby gender. Parametric distributional assumptions (e.g., normality) will be checked and other distributions will be considered prior to transformations and non-parametric methods. Baseline descriptive statistics (e.g., means, standard deviations, frequencies, proportions) will be presented overall and by treatment group. No inferential statistics will be presented. Baseline variables that appear to be different between the two treatment groups willbe adjusted for in sensitivity analyses. Linear mixed models utilizing all data (baseline, 6- and 12-month) adjusting for gender will be used to analyze the primary outcome. We will test the time by treatment groupinteraction term at the 10% level of significance. If this term is significant, we will utilize a contrast term at 6-months to test the primary hypothesis. If this term is not significant, we will use the time-averaged treatmentdifference to test the primary hypothesis. Generalized linear mixed models (e.g., log link for binary outcomes; identity link for continuous outcomes) adjusting gender will be used to analyze secondary outcomes. Like the primary outcome, we will test for treatment by time interactions at the 0.10 level. If significant we will use contrast at 6- and 12-months to assess for differences; if there is no interaction, then a time-averaged approach will be utilized, and we will have more power to detect the proposed effect sizes. To control for false discovery forsecondary outcomes, we will use the Benjamini and Hochberg method[224]. We will make attempts to limit theamount of missing data through stipend payments to participants, but we expect that we will encounter missingdata. We will employ mixed models approaches, which utilize all available data and assume missing at random.We plan to assess the robustness of our results under a missing not a random assumption using pattern mixture models. We will also consider utilizing inverse probability weighting to account for missing data, if necessary. Exploratory analyses will focus on mediation analyses and explore tests of both the direct effect of treatment on the mediator and the indirect effect as well as the mediated effects of factors in between primary and secondaryoutcomes as predicted in the model (see Figure 2)[225].

Qualitative data analysis: Transcriptions and field-notes will be analyzed and interpreted using qualitative thematic analysis procedures in which coding and sub-coding categories are derived iteratively from transcribeddata, integrating inductive and deductive approaches[226, 227]. We will then integrate qualitative and quantitative findings to help us best understand the lived experience of financial difficulties related to incarceration for the target group, and the impact of the intervention on those difficulties. One way we will do this is by synthesizing the data to build participant profiles that identify constellations of demographic characteristics, incarceration histories and financial difficulties most associated with both improved financial well-being, and with lack of such improvement. We will do this by identifying the above associations using the quantitative analyses and using the qualitative data to probe more deeply into how those associations are experienced in people's lives.

7.3 All analyses will be performed according to intent-to-treat with an overall type I error rate of 5% (two- sided) using SAS (Cary, NC) and R (R Project). All analyses will follow the design and account for stratification by inmate status. Parametric distributional assumptions (e.g., normality) will be checked and other distributions will be considered prior to transformations and non-parametric methods. Baseline descriptive statistics (e.g., means, standard deviations, frequencies, proportions) will be presented overall and by treatment group. No inferential statistics will be presented. Baseline variables that appear to be different between the two treatment groups will be adjusted for in sensitivity analyses. Linear mixed models utilizing all data (baseline, 6- and 12- month) adjusting for inmate status will be used to analyze the primary outcome. We will test the time by treatment group interaction term at the 10% level of significance. If this term is significant, we will utilize a contrast term at 6-months to test the primary hypothesis. If this term is not significant, we will use the time-averaged treatment difference to test the primary hypothesis. Generalized linear mixed models (e.g., log link for binary outcomes; identity link for continuous outcomes) adjusting for inmate status will be used to analyze secondary outcomes. Like the primary outcome, we will test for treatment by time interactions at the 0.10 level. If significant we will use contrast at 6- and 12-months to assess for differences; if there is no interaction, then a time-averaged approach will be utilized, and we will have more power to detect the proposed effect sizes. To control for false discovery for secondary outcomes, we will use the Benjamini and Hochberg method. We will make attempts to limit the amount of missing data through stipend payments to participants, but we expect that we will encounter missing data. We will employ mixed models approaches, which utilize all available data and assume missing at random. We plan to assess the robustness of our results under a missing not a random assumption using pattern mixture models. We will also consider utilizing inverse probability weighting to account for missing data, if necessary. Exploratory analyses will focus on mediation analyses and explore tests of both the direct effect of treatment on the mediator and the indirect effect as well as the mediated effects of factors in between primary and secondary outcomes as predicted in the model.

7.3.1 Secondary Objective Analyses (if applicable)

Explain how data will be analyzed to evaluate the secondary study objectives, if applicable.

7.3.2 Analysis of Subject Characteristics (if applicable)

Specify descriptive analysis to define subject population(s).

7.3.3 Interim Analysis (if applicable)

If an interim analysis will be done, explain the rationale, timing, and impact to the study. Include any stopping rules that would determine if the study should be discontinued.

7.4 Data Relevance

To accomplish our aims, we have designed two components of the **Financial Health and Mental Health after Incarceration** research project, involving data collection from human subjects: (1) Enrollment and data collection of participants in the intervention (n=204), including randomization of participants who will receive regular financial capability support, (2) training of existing coaches working for the New Haven Financial Empowerment Center (NHFEC) and training for service providers currently working with the target population at various points along the criminal justice trajectory, including staff of jail diversion and forensic psychiatry programs, pre-sentencing programs, public defenders, in-prison counselors, probation and parole officers, and staff of transitional housing and reentry programs, to enable them to address common financial problems that people may face, and to understand when a referral to financial coaching is possible/appropriate. We will then conduct a series of four focus groups with the trained providers (n=40).

We will utilize a parallel-group design for the randomized control trial (RCT). Randomization will take place at the individual level. Participants will be randomized to treatment as usual (regular financial capability support) or treatment as usual with peer support using a 1:1 allocation ratio. The randomization scheme will be generated by the study statistician and given to the data manager for implementation using the Research Electronic Data Capture (REDCap) randomization module to maintain allocation concealment. The randomization will be stratified by gender community supervision status and carried out using random permuted block sizes of 2,4, and 6. Participants will be randomly allocated after completion of the baseline assessment.

7.5 Data Coding

All collected participant data will be assigned a code via REDCap. Access to the link between participant and code will only be available to the research team.

7.6 Data Analysis Tools

Yes, all analyses will be performed according to intent-to-treat with an overall type I error rate of 5% (two-sided) using SAS software.

7.7 Data Monitoring

Dr. Harper (MPI) is responsible for monitoring all study activities on a day-to-day basis. Dr. Harper will hold weekly research team meetings and discuss protocol and implementation issues, review adverse events, and discuss preliminary or incidental findings. We will also meet quarterly with our Advisory Council and ISM. Data analysis will be ongoing throughout the research period. Trial stopping rules include a greater than expected morbidity or mortality rate, patterns of unanticipated negative findings associated with the intervention, or interference/hindering of the administration of routine medical and behavioral health care that cannot be resolved by an NIH-approved protocol or DSMP change.

7.8 Handling of Missing Data

We will make attempts to limit the amount of missing data through stipend payments to participants, but we expect that we will encounter missing data. We will employ mixed models approaches, which utilize all available data and assume missing at random. We plan to assess the robustness of our results under a missing not a random assumption using pattern mixture models. We will also consider utilizing inverse probability weighting to account for missing data, if necessary.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Participant confidentiality and privacy is strictly held in confidence by the participating investigators, their staff, and the sponsor(s)/funding agency. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence.

All research activities will be conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB), regulatory agencies or study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for the participants in this study. The study site will permit access to such records.

The study participant's contact information will be securely stored at each study site for internal use during the study. 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 the reviewing IRB, Institutional policies, regulatory, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Yale University Program for Recovery and Community Health. 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 will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Yale University Program for Recovery and Community Health.

8.2 Data Quality Assurance

Although Dr. Harper assumes primary and ultimate responsibility for monitoring protocol implementation, safety, and adherence to the DSMP, she will be aided by our program's internal safety officer (Kimberly Blackman) and the Project Manager. Together, they will ensure that procedures are streamlined for the identification and reporting of adverse and unexpected events across recruitment sites. Dr. Harper and Ms. Blackman are responsible for all quality assurance measures for subject recruitment, enrollment, enrollment targets, and for the validity and integrity of the data in compliance with Good Clinical Practice (GCP) and applicable regulatory requirements.

8.3 Data or Specimen Storage/Security

All electronic data collected will be via REDCap. In the case, we use paper and pen data, the data will be rendered de-identified and kept in a secure locked cabinet, in a secure office.

8.4 Study Records

Research materials and data will be obtained from quantitative assessments online via RedCap (a secure platform approved by the Yale University IRB). If necessary, these assessments can be provided by pen and paper, and transferred into RedCap by research assistants, if some participants with limited technological literacy request support. Qualitative interview data will be obtained via video-audio conference using a HIPPA compliant platform (approved by Yale University IRB) or by telephone or in-person interviews digitally audio recorded. Focus groups with facilitators will be recorded, and the audio files will be transcribed for qualitative analysis.

8.5 Access to Source

How research material, data, and records will be obtained

Research materials and data will be obtained from quantitative assessments online via RedCap (a secure platform approved by the Yale University IRB). If necessary, these assessments can be provided by pen and paper, and transferred into RedCap by research assistants, if some participants with limited technological literacy request support. Qualitative interview data will be obtained via video-audio conference using a HIPPA compliant platform (approved by Yale University IRB) or by telephone or in-person interviews digitally audio-recorded. Focus-groups with facilitators will be recorded and the audio files will be transcribed for qualitative analysis.

Whether any private identifiable information will be collected in the proposed research project

Private identifiable information will be collected in the proposed research study. Personal health information will include contact information (e.g., name, address, phone number, email address, date of birth), personal responses to assessments during the study, criminal justice involvement history, and personal responses to qualitative questions about experiences and histories with the criminal justice and mental health system, when relevant.

8.6 Retention of Records

De-identified data will be kept indefinitely.

8.7 Data and Safety Monitoring Plan

We have designed our Data Safety and Monitoring Plan (DSMP) with careful consideration of the relative risks to all participants and the nature of the trial. Although our research study and intervention itself poses “no greater than minimal risk”, it does involve participants who use substances. Thus, in accordance with NIH guidelines and federal regulations for conducting research involving persons who with criminal justice involvement, we have put additional monitoring and protections in place to promptly identify and respond to adverse events. This includes the identification of an Independent Safety Monitor (ISM)—Dr. Madelon Baranowski, a Professor in the Department of Psychiatry, Yale School of Medicine, and Director of the Division of Law and Psychiatry at the Connecticut Mental Health Center —who will provide additional oversight of all research activities, as deemed necessary by NIH. The ISM will advise Dr. Harper and NIH of any safety concerns, review adverse events, and make recommendations to the study team on design and implementation issues. Once finalized and approved by NIH and the Yale IRB, this DSMP will not be

modified without prior review and approval from NIH. If the benefit-risk analysis changes, we will work closely with the NIH Program Officer to modify our clinical protocols and DSMP accordingly.

A summary of our research protocol, including a description of participants, sites, measures, sample size, sources of data, inclusion/exclusion criteria, foreseeable risks, consent procedures, protections of privacy, and data security procedures can be found in the Protection of Human Subjects Section and the Research Strategy.

Trial Safety. Events that would preclude a participant from continuing the intervention include discontinuation or withdrawal from the research study by the participant; aggressive or threatening behavior toward research staff; a Serious Adverse Event (SAE) that is related to the intervention itself; or other events or circumstances about which we are advised by the ISM, IRB, or NIH that participation in the study should be terminated.

The Yale University Policy on Conflict of Interest requires that assessment and disclosure of conflict of interest occur on an annual basis or as a new conflict of interest emerges. Potential conflicts of interest identified among any member of the research team or the ISM will be immediately reported to the Yale Conflict of Interest Committee who will advise on methods of resolving the conflict, including, if need be, removal from the grant. We will ensure compliance with the DSMP at the recruitment sites by working closely with facilitators to ensure that all are familiar with, and upholding, the DSMP. Reporting of adverse events, incidental findings, and other relevant study information will be shared across recruitment sites.

9 Study Considerations

9.1 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required.

Study closure will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale policies.

9.2 Research Personnel Training

Researchers assisting with the conduct of research activities are certified in CITI Human Subjects Protective Training and HIPPA guidelines to ensure study adherence to study procedures and their responsibility to carry out the protocol.

9.3 Study Monitoring

Although Dr. Harper assumes primary and ultimate responsibility for monitoring protocol implementation, safety, and adherence to the DSMP, she will be aided by our program's internal safety officer (Kimberly Blackman) and the Project Manager (Dr. Flanagan, also co-investigator). Together, they will ensure that procedures are streamlined for the identification and reporting of adverse and unexpected events across recruitment sites. Dr. Harper and Ms. Blackman are responsible for all quality assurance measures for subject recruitment, enrollment, enrollment targets, and for the validity and integrity of the data in compliance with Good Clinical Practice (GCP) and applicable regulatory requirements. Dr. Flanagan is responsible for interim, annual, and final analyses of program components, targets, and outcomes. As noted above, we have also identified an independent, external ISM (Dr. Baranowski) who can provide additional guidance and oversight of the DSMP and research protocols.

9.4 Unanticipated Problems and Protocol Deviations

A protocol deviation is any noncompliance with the protocol. 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 investigator to identify and report deviations within <specify number> working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing Institutional Review Board (IRB) per their policies.

Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

- *Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;*
- *Related or possibly related to participation in the research ("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); and*

- *Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.*

If the study team becomes aware of an unanticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB by IRES platform.

The UP report will include the following information:

Protocol identifying information: protocol title and number, PI's name, and the IRB project number;

- *A detailed description of the event, incident, experience, or outcome;*
- *An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;*
- *A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.*

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- *UPs will be reported to the IRB within 72 hours of the investigator becoming aware of the event.*

9.5 Study Discontinuation

Events that would preclude a participant from continuing the intervention include discontinuation or withdrawal from the research study by the participant; aggressive or threatening behavior toward research staff; a Serious Adverse Event (SAE) that is related to the intervention itself; or other events or circumstances about which we are advised by the ISM, IRB, or NIH that participation in the study should be terminated

9.6 Study Completion

The completion date is estimated to be four years from IRB approval.

9.7 Conflict of Interest Management Plan

The Yale University Policy on Conflict of Interest requires that assessment and disclosure of conflict of interest occur on an annual basis or as a new conflict of interest emerges. Potential conflicts of interest identified among any member of the research team or the ISM will be immediately reported to the Yale Conflict of Interest

Committee who will advise on methods of resolving the conflict, including, if need be, removal from the grant. We will ensure compliance with the DSMP at the recruitment sites by working closely with facilitators to ensure that all are familiar with, and upholding, the DSMP. Reporting of adverse events, incidental findings, and other relevant study information will be shared across recruitment sites.

9.8 Funding Source

National Institute of Health (NIH)

9.9 Publication Plan

We will ensure that the clinical trial conducted under this award is registered and study results are submitted to ClinicalTrials.gov as outlined in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information policy and according to timelines stated in the policy. Informed consent documents for the pilot clinical trial will include a specific statement regarding posting of clinical trial information at ClinicalTrials.gov. Yale University has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

Access to databases generated under the project will be available for educational, research and non-profit purposes. Such access will be provided using web-based applications, as appropriate, to avoid or minimize associated costs. Publication of data shall occur during the term of the project, if appropriate, or at the end of the project, consistent with normal scientific practices. Research data which documents, supports and validates research findings will be made available after the main findings from the final research data set have been accepted for publication. Such research data will be redacted to prevent the disclosure of personal identifiers. All data obtained from participants will also be shared via the National Database for Clinical Trials related to Mental Illness (NDCT). In enrolling participants, necessary information will be obtained to generate a Global Unique Identifier (GUID). The necessary strategies to develop the GUID will be achieved with the tools available at the NDCT website. Raw data will be submitted every 6 months until the end of the grant. Plain language text will be added to the consent form to inform participants and obtain their consent to share data with NDCT.
The plan allows us to disseminate findings to participants, communities, banks, DOC, DMHAS, churches other stakeholders, staff at local mental health authorities, community members, researchers, and other community agencies. The advisory and CBPR team will assist with targeting our dissemination efforts and will be involved in sharing the information in the community, to organizations and banks, and at conferences targeted to researchers, providers, community leaders, and for people with histories of incarceration. A preliminary dissemination plan involves the following:

- Provide reports to NIH to share successes and challenges.

- Share findings with the participants and other service users. Oftentimes, individuals are involved in research studies sponsored by Yale and other institutions and never get to hear about the findings. We will translate the report in a more “accessible” language so that non-researchers can understand the reports. Hearing from fellow CBPR and advisory team members throughout the project will also keep us accountable to the purpose of the project, which is ultimately to better support individuals. We plan to have dissemination report presentations at 4 points during the study particularly to share the information as part of the CBPR process.
- Share findings with NIH, SAMHSA, CMS, CDC, DOC, Banking Institutions, and other national organizations that will be interested in these findings.
- Share the findings with experts throughout so that they are aware of the process and to learn about the challenges and successes.
- Share findings with DMHAS, our state mental health authority, and providers in the National Association of State Mental Health Program Directors (NASMHPD), DOC, so they have access to this timely information.
- Share study findings and replication tools.

10 Appendices

Appendix #	Title	Section	Topic

11 List of Tables

APPROVED BY THE YALE UNIVERSITY IRB 3/13/2024