IGNITE

A Randomized Controlled Trial of Concentrated Investment in Black Neighborhoods to Address Structural Racism as a Fundamental Cause of Poor Health

Study Protocol

April 2023

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1. Abstract

Black Americans in the US fare worse across nearly every health indicator compared to White individuals. In Philadelphia, the location of this study, these health disparities culminate in a stark longevity gap, with average life expectancies in poor, predominantly Black neighborhoods being 20 years lower than in nearby affluent, predominantly White neighborhoods. We will conduct a cluster randomized controlled trial (RCT) of a suite of place-based and financial-wellbeing interventions at the community, organization, and individual/household levels that address the social determinants of racial health disparities. At the community level, we address underinvestment in Black neighborhoods by implementing vacant lot greening, abandoned house remediation, tree planting, and trash cleanup. At the organization level, we partner with community-based financial empowerment providers to develop cross-organizational infrastructure to increase reach and maximize efficiency. At the individual/household levels, we increase access to public benefits, financial counseling and tax preparation services, and emergency cash assistance. We will test this "big push" intervention in 60 Black neighborhood microclusters, with a total of at least 480 adults and 480 children across up to 720 households. We hypothesize that this "big push" intervention will have significant impact on overall health and wellbeing.

2. Overall objectives

The objective is to develop and test a concentrated suite of place-based and financial well-being interventions at the community, organization, and individual levels to address structurally-mediated racial health disparities.

3. Aims

3.1 Primary outcomes

Overall health and psychological distress of participants.

3.2 Secondary outcomes

The secondary outcomes are described in detail in Table 1 below.

4. Background

Black individuals in the United States fare worse than White individuals across almost every social, economic, and health indicator. The Black health disadvantage starts at birth, reflecting the cumulative toll of racialized social stressors and healthcare discrimination on maternal health and resulting in higher rates of preterm birth and low birth weight. Black youth are disproportionately exposed to environmental toxins such as lead and adverse childhood events such as financial hardship and neighborhood violence. Black adults have higher rates of chronic disease, including diabetes, hypertension, as well as many cancers. These and other forces culminate in a stark racial longevity gap: in Philadelphia, the location of this study, life expectancy for people living in a poor, predominantly Black neighborhood is 20 years lower than for people living in a nearby affluent, predominantly White neighborhood.

The fundamental cause of these striking and pervasive disparities is structural racism – the confluence of deep historical, institutional, cultural, and ideological forces that unequally distribute resources and risks across racialized groups. Structural racism patterns health by affecting a range of interconnected, mutually reinforcing social determinants of health at the national, neighborhood, household, and individual levels. Most notably, longstanding, systematic disinvestment has resulted in highly segregated Black neighborhoods with dilapidated

environmental conditions and severe economic insecurity within Black households, leading to a "feedback loop of concentrated racial disadvantage," all of which have been strongly tied to poor health.

Most interventions seeking to address racial health disparities focus on individual-level behaviors and outcomes, or individual channels by which structural racism harms health. However, by failing to address upstream social determinants, these interventions have had limited population level impact. A multi-level, multi-component intervention package focused on a range of social determinants of health is necessary to meaningfully address structural racism as a fundamental cause of racial health disparities.

5. Study design

5.1 Design

This is a cluster randomized controlled trial. We will enroll 60 neighborhood microclusters in the study. Half of the study clusters will be randomized to the intervention and the other half to the control group.

5.2 Study duration

The study is expected to begin in September 2022 and participants will continue in the study for 24 months. The study will last for 5 years. Year 1 will include protocol development and cluster selection. Participant selection and baseline data collection will start in Year 2 and last 9 months. The place-based and financial well-being interventions will begin quarter 3 of Year 2 and last 18 months, followed by follow-up data collection. Qualitative interviews will be conducted in Year 3. Data analysis occurs from Year 2 into Year 5. Year 5 will involve final data analysis, manuscript preparation and submission, and dissemination of study findings.

5.3 Target population

Our population will include adults living in our target Philadelphia neighborhood microclusters.

5.4 Accrual

We will enroll at least 480, and up to 720, adults from 60 neighborhood microclusters in the study, half of which will be randomized to the intervention and half to the control. If more than one household resident is interested and eligible in the study, the person with the most recent birthday will be enrolled. One participant per household is eligible.

If there are one or more children ages 3-17 living in the household, this child's caregiver will also be given the option of completing an additional survey regarding their child's health. We will enroll adult caregivers of 480 children ages 3-17, including the 480 adults described above and up to 240 additional participants.

5.5 Key inclusion criteria

To be eligible patients must:

1. Be at least 18 years of age
2. Have the ability to communicate via text messaging
3. Be comfortable communicating in English
4. Be a permanent resident of the home where they are to be enrolled
5. Have knowledge of their household finances

5.6 Key exclusion criteria

1. Individuals who plan to move out of the study microcluster within 6 months
2. Individuals who are unable to fully consent and participate based on CC team assessment

5.7 Key inclusion criteria for IGNITE Kids Caregivers

To be eligible caregivers must:

1. Be at least 18 years of age
2. Be the primary caregiver of one or more children ages 3-17 years
3. Have the ability to communicate via text messaging
4. Be comfortable communicating in English
5. Be a permanent resident of the home where they are to be enrolled
6. Have knowledge of their household finances

5.6 Key exclusion criteria

1. Individuals who plan to move out of the study microcluster within 6 months
2. Individuals who are unable to fully consent and participate based on CC team assessment
3. Individuals who are not the primary caregivers of children ages 3-17 years

6. Subject recruitment

Participant recruitment will commence in September 2022 and will run through March 2024. Recruitment in control and intervention microclusters will occur simultaneously. The data analyst who performed the randomization will randomize microcluster order (stratified by intervention and control status and city section) to determine the order in which recruitment occurs.

Several Community Coordinator (CC) teams will be recruiting participants. A given team of two will remain in a microcluster until a total of 12 participants are fully enrolled in that microcluster. They will then move to the next microcluster on the randomly generated list. Multiple microclusters will be undergoing enrollment simultaneously. The CC team will be blinded to what arm of the trial the microcluster is in until all participants are enrolled. Participants will also be blinded until after everyone in that cluster is enrolled.

When starting recruitment in a new microcluster, the CC team will first place door knockers on all homes within the microcluster boundaries to alert neighbors to the presence of the study team in the neighborhood. They will then begin door-to-door recruitment at a pre-determined house that is closest to the geographic center of the study microcluster. They will follow a pre-determined route throughout the neighborhood that includes walking up one side of the street and back down the other side of the street before moving on to an adjacent block, and the next adjacent block, etc. The block order will be pre-determined by the data analyst performing randomization to where blocks will be ordered as closet to concentrically in a clockwise manner from the first block.

If more than one household resident is interested and eligible in the study, the person with the most recent birthday will be enrolled. One participant per household is eligible. The CC team will conduct an informed consent with all participants. The CC team will then administer a demographic and baseline survey and directly enter data into REDCap. If the resident is interested in the study but is not available or able to complete the baseline survey at the time of the first encounter, CC team will conduct the Informed Consent Process (resident will sign the Informed Consent Form) and then identify a time to reschedule completion of the survey. If necessary, the CC team can schedule to meet with the resident virtually to complete the baseline survey.

Completion of the baseline survey indicates resident is fully enrolled in the study and is to be considered the official date of enrollment.

If there are one or more children ages 3-17 living in the household, the child or children's primary caregiver will be given the option of completing an additional follow-up survey regarding their child's health and well-being. One participant per household is eligible to complete the children's health and well-being survey for up to three children residing in the household. If more than three children ages 3-17 reside in the household, the enrolled caregiver will be asked to complete the survey for the three children with the most recent birthdays. We will enroll adult caregivers of approximately 480 children ages 3-17. To meet this goal, approximately up to 240 additional caregivers will be enrolled. Towards this end, after enrollment of adult subjects is complete within a microcluster, CC teams will continue to enroll caregivers from homes within a microcluster with which contact has not already been made. Enrollment will end when either enough caregivers are enrolled for up to 10 children per microcluster or two weeks after adult enrollment closes within the microcluster.

Subject compensation

Participants will be compensated $40 after the baseline survey using ClinCards, $15 after a 6 month check in, $15 after a 12 month check in, $15 after an 18 month check in, and $40 after a follow up survey. Participants with children who agree to complete a supplemental follow-up survey regarding their children's health will receive an additional $20 per child (up to 3 children per household). Follow up data collection will occur between September 2024 and March 2025, with each participant surveyed 24 months after their initial enrollment date. If participants are selected to participate in an additional qualitative feedback interview, they will receive $40 compensation.

8. Study procedures

8.1 Consent

Informed consent will be obtained in person at the participant's home using REDCap, a HIPAA compliant web-based platform. The potential participant will receive information explaining the purpose of the study and what would be required of the participant, and that participation is voluntary. Any questions the potential participant may have will be addressed. The community coordinator team will convey important and relevant information about the study, disclose all risks and benefits, fully describe the study procedures relevant to participants, answer all questions, and enable each participant to make a competent, informed decision about volunteering for the study, free from undue influence.

In response to a global or regional epidemic (e.g., COVID-19) or other extreme circumstances (e.g., natural disaster, medical emergency), the informed consent process may be conducted remotely to minimize potential risks to participants. The informed consent process may also be conducted remotely if participants are interested in the study but are not available during our normal recruitment hours. To aid in this process, a copy of the informed consent form can be provided to the participant in advance of the consent discussion, either in person when they are approached at their residence or via email. The informed consent discussion will be conducted via telephone or a video-conferencing platform (e.g., Zoom). To ensure the privacy of the participant, the community coordinator will conduct the remote informed consent process from a private location, while the participant is expected to be in their home. The participant will have ample time to consider their participation and consult with others (e.g., family, friends) prior to signing the informed consent. Once the consent discussion is complete, REDCap will be used to document the participant's consent and capture a hand signature using a

finger, stylus, or mouse. The community coordinator will review the REDCap form to make sure the signature has saved.

8.2 Procedures

Site selection

Census tract selection

We created a list of all census tracts (n=384) in Philadelphia, PA using the 2019 American Community Survey (ACS). Using 5-year population estimates, we determined the total number of Black residents for each tract by combining the number of residents who identified as Black only and Black in addition to one or more races. We then sorted the census tracts based on percent of Black residents from high to low. To ensure that our study focused on predominantly Black neighborhoods, census tracts with a high proportion of Black residents (80% or more of the population; n=99) were deemed eligible for inclusion in the study.

Another goal of the trial is to reach the most economically distressed neighborhoods and households. To achieve this, we included only those census tracts where at least 39% of households had an income at least 200% below Federal Poverty Level (FPL). This threshold mirrors the citywide proportion of families living at 200% or below of FPL. Seventy five of the 99 predominantly Black census tracts met this inclusion criteria (one census tract met this criteria but was excluded as it was in the South Philadelphia section of Philadelphia which is geographically dissimilar from the rest of the tracts).

Block random sampling

Neighborhood microclusters (hereafter, microcluster) served as the intervention unit for the study. To form these microclusters, a master list of every block, or street segment from one intersection to the next intersection, in the 75 eligible census tracts was created. A total of 8,462 blocks were included in the master list. A shapefile of selected blocks was imported into R. A random block was chosen as an index block and a 0.125 (one eighth) mile diameter buffer was created around that block. All other blocks that fell within this radius were used to form a microcluster of geographically proximal blocks. A block was included in the microcluster if at least half of the street segment fell within the microcluster boundaries. This microcluster formed a study area. All blocks that were included in the microcluster were removed from the master list to ensure no overlap of microclusters. Next, an additional 0.125-mile exclusion zone buffer was created on all sides of each microcluster. The purpose of the exclusion zone was to create an additional buffer between microclusters to minimize potential spillover effects from the interventions. This process was then repeated until 60 total non-overlapping microclusters were created, stratified by section of the city (West and North), so that approximately 30 microclusters were in each city section.

Our goal was to have a final set of microclusters that minimized overlap of microcluster exclusion zones to reduce potential spillover and contamination effects across trial arms. To do this in a random manner, the process to create 60 study microclusters with 0.125-miles exclusionary zones was repeated 1,000 times to create 1,000 unique maps. An analysis was run to determine the total area of exclusion zone buffer overlap for each of the 1,000 microcluster map iterations, which was then ordered from lowest to highest. We then selected the bottom microcluster iterations with the lowest exclusion zone overlap. From this list, one iteration was selected at random to determine final study sites.

Randomization

We randomly assigned the 60 microclusters to treatment (intervention, n=30 microclusters) and control (non-intervention, n=30 microclusters) groups. Prior to randomization, microclusters were stratified by city section

(West and North). The land area and number of streets in each section was near-equal, allowing for stratification pre-constrained randomization.[1]

Within the city section strata, we conducted a covariate-constrained randomization process in order to ensure balance between microclusters randomized to intervention and those randomized to control based on relevant sociodemographic variables. Covariate-constrained randomization quantifies baseline imbalance of microcluster-level covariates (both categorical and continuous) across all microclusters using a balance metric and then randomly selects one randomization schema from those with acceptable balance. Furthermore, the intraclass correlation coefficient calculation – a measure of reliability – remains unaffected under a constrained randomization model.[2]

We chose the following covariates to balance on: age (categorized by shares under age 19, 19-49, 50-64, and 65 and above); gender; median income; unemployment rate; amount of vacancy; and tree canopy. We did not balance on race/ethnicity (e.g., % Black) or poverty rates, since initial criteria for study site selection focused on census tracts whose populations were at least 80% Black and with elevated poverty rates. The covariates were measured based on their distribution of means by each microcluster using block group data from the US Census Bureau's 2020 ACS. Each microcluster's mean is the weighted mean for the covariates based on percent of land area in each census block group in which the microcluster sits. A microcluster could be in one census block group or could cross over 2 or 3 census block groups. Following the literature, we used a threshold of 0.2 for standardized mean differences in the covariates.

We used the -cvcrand- package, specifically the -cvrall- function, in R to calculate the final covariate balance metric and selection schema at random after covariate balance by cluster was achieved.[2]

Enrollment

Participant recruitment will commence in September 2023 and will run through May 2023 (or until we enroll at least 480, but no more than 720, in the main trial). Recruitment in control and intervention microclusters will occur simultaneously. The data analyst who performed the randomization will randomize microcluster order (stratified by intervention and control status and city section) to determine the order in which recruitment occurs.

Several Community Coordinator (CC) teams will be recruiting participants. A given team of two will remain in a microcluster until at least 8participants are fully enrolled in that microcluster. They will then move to the next microcluster on the randomly generated list. Multiple microclusters will be undergoing enrollment simultaneously. The CC team will be blinded to what arm of the trial the microcluster is in until all participants are enrolled. Participants will also be blinded until after everyone in that cluster is enrolled.

When starting recruitment in a new microcluster, the CC team will first place door knockers on all homes within the microcluster boundaries to alert neighbors to the presence of the study team in the neighborhood. They will then begin door-to-door recruitment at a pre-determined house that is closest to the geographic center of the study microcluster. They will follow a pre-determined route throughout the neighborhood that includes walking up one side of the street and back down the other side of the street before moving on to an adjacent block, and the next adjacent block, etc. The block order will be pre-determined by the data analyst performing randomization to where blocks will be ordered as closet to concentrically in a clockwise manner from the first block.

For a given house, a potential participant will be screened by the CC team to determine eligibility:

Key Inclusion Criteria:

- At least 18 years of age
- Have the ability to communicate via text messaging

- Individuals comfortable communicating in English
- A permanent resident of the home where they are to be enrolled
- Have knowledge of their household finances

Key Exclusion Criteria:

- Individuals who plan to move out of the study microcluster within 6 months
- Individuals who are unable to fully consent and participate based on CC team assessment

If more than one household resident is interested and eligible in the study, the person with the most recent birthday will be enrolled. One participant per household is eligible. The CC team will conduct an informed consent with all participants. The CC team will then administer a demographic and baseline survey and directly enter data into REDCap. Participants will be compensated $40 after the baseline survey using ClinCards, $15 after a 6 month check in, $15 after a 12 month check in, $15 after an 18 month check in, and $40 after a follow up survey. Follow up data collection will occur between September 2024 and March 2025, with each participant surveyed roughly 24 months after their initial enrollment date.

For all households including one or more children ages 3-17 living in the household, the child or children's primary caregiver will be asked to complete an additional follow-up survey regarding their child's health and well-being, for up to three children per household. If more than three children ages 3-17 reside in the household, the enrolled caregiver will be asked to complete the survey for the three children with the most recent birthdays. Participants who complete the follow-up survey regarding children's health will be compensated $20 after survey completion.

To support recruitment efforts, we will partner with community organizations to widen the reach of study promotion and to improve dissemination of recruitment materials, particularly in communities where recruitment is found to be difficult. We will also use a community-facing website to promote the study and increase screening for enrollment.

Respondent Driven Sampling

Respondent driven sampling will be implemented to drive enrollment when Community Coordinators identify that completing enrollment (i.e., reaching at least 8 participants) is difficult in a particular microcluster. This strategy will be implemented only as a contingency

Participants will then be invited to refer individuals who they think may be willing to participate in the study. If those referrals meet eligibility criteria and are successfully enrolled, the participant who made the initial referral will receive a payment of $15 via their ClinCard for that successful referral.

Participants can make an unlimited number of referrals, but only up to 2 referrals will be enrolled per participant (to limit referral networks at a max of four networks per cluster.)

Intervention

Place-Based Interventions

Our suite of place-based interventions consists of four separate interventions which will all be performed simultaneously in all of the intervention microclusters. The four interventions are: vacant lot greening, tree planting, weekly trash pickup, and abandoned house remediation. The first three will be performed through the Pennsylvania Horticultural Society (PHS), while the last will be performed through the City of Philadelphia.

After microclusters have been selected and randomized to the intervention arm (n=30), we will conduct an inventory of the locations of existing vacant lots, abandoned houses, and tree canopy. All place-based interventions will start in April 2023. See below for protocol for each intervention including the intervention timeframe for each.

Vacant lot greening. We will green a total of 150 vacant lots in the intervention microclusters (roughly 3-5 lots totally up to 5000 square feet per microcluster). Vacant lot greening is a standard, reproducible intervention involving (a) the removal of trash and debris, (b) grading of the land, (c) planting new grass and for some lots a small number of trees, and (d) installing a low wooden perimeter fence.[3] Vacant lots will be greened between April and June 2023. During the growing season (April-October), bi-monthly maintenance is performed which involves mowing and picking up trash between July 2023 and August 2024. In order to determine which vacant lots will be greened within each microcluster, we will first use a master list of vacant lots provided by PHS and overlay this list with our microcluster boundaries. Vacant lots are eligible for greening if they are in violation of city ordinance (eg. over 10 inches of vegetation) and if they show no signs of active maintenance or ownership (eg. the presence of a locked chain fence). Within each microcluster we will green up to 5 vacant lots totalling up to 5000 square feet of vacant space. We will first eliminate vacant lots over 5000 square feet. If lots in a given microcluster total more than 5000 square feet we will randomly sort the list of vacant lots and select the top 3-5 to total up to 5000 square feet. We will give priority to lots that are contiguous (eg. If a given parcel of land is selected that has 2 other vacant parcels connected to it, we will also include those adjacent parcels before moving down the list to the next vacant lot). If lots in a given microcluster total less than 5000 square feet, we will then inventory vacant lots that are in PHS Community LandCare program, which are vacant lots that receive mowing and trash cleanup, but previously did not receive the full vacant lot treatment described above. We will randomly select vacant lots from this pool to receive the full vacant lot greening treatment to get up to 5000 square feet of vacant lots total in the microcluster. Lots determined eligible by PHS are sent to the City of Philadelphia for permission to green. Some lots sent to the City may ultimately be deemed ineligible and would not receive the greening intervention.

Tree planting. We will plant a total of 300 trees in the intervention microclusters during this study, or roughly 10 trees per cluster. Trees will be planted between September and October 2023, with monthly watering occurring between planting and August 2024 during the growing season. We anticipate that some clusters may receive less than 10 trees and other clusters will receive more than 10 trees based on availability of planting opportunities. Trees will be planted and maintained through PHS. In Philadelphia, permission is needed from the owner of a property to plant a tree. After all participants in an intervention microcluster are enrolled and the microcluster randomization is revealed to the community coordinator team, all participants who indicated they were interested in a tree will have a tree planted in front of their residence based on the following criteria: (a) there is an open space for a tree, (b) there are no physical barriers to tree planting (eg fire hydrant), and (c) the owner of the property lives in the home and is able to give permission to plant a tree. If the participants rents the property, we will determine if they would like to seek permission from the landlord. After we determine which study participants are eligible for a tree, we will then canvas the neighbourhood microcluster to find other residents, businesses, places of worship, etc in the cluster who are not participants in the study who want a tree planted, for a total of 12-15 potential tree planting opportunities. We know that some tree planting sites will ultimately not be eligible for planting which is why we will initially select 12-15 sites with the aim of planting 10 trees per cluster. This list will then be sent to the PHS who will work with the City of Philadelphia to determine which physical locations are eligible for a tree. For example, sometimes there are water lines too close to the side-walk surface that make a location ineligible.

Trash cleanup. We will provide weekly trash cleanup in all public spaces in the blocks included in our intervention clusters between April 2023 and August 2024. Public space includes on streets and sidewalks, but not into private front yard space. Although the city performs weekly trash pickup, this is limited to trash that is

in garbage cans, leaving neighborhoods with a significant trash burden that does not fall under the purview of regular sanitation. Trash cleanup will occur through PHS.

Abandoned house remediation. We will remediate 90 abandoned houses in the intervention clusters during this study, or approximately 3 houses per cluster. Remediation will take place between April and August 2023. Abandoned house remediation follows a standard protocol and includes (1) replacement of plywood boards or missing/broken doors and windows on the front façade of the house with new, standard, exterior, front entryway, wooden doors and standard, double-hung, wooden windows; (2) removal or replacement of deteriorated structures on front building façade; and (3) cleaning and graffiti removal on building façade. A master list of publicly owned abandoned houses in our study intervention clusters will be compiled using publicly available data from the City of Philadelphia. We will not include privately owned abandoned houses in the trial. If there are more than 3 eligible abandoned houses in a cluster, we will randomly sort the list and select the top 3 houses to remediate. Remediation will be conducted through the City of Philadelphia.

Individual and Household-Level Financial Interventions

Participants in the intervention group will be directly connected to three Philadelphia-based community-based partners who specialize in improving access to financial services and public benefits among low-income individuals. The partners and the services provided are:

- Clarifi – provides free financial counseling, starting with a detailed intake process that includes elicitation of financial goals and development of an action plan over multiple sessions.
- Benefits Data Trust (BDT) – provides free integrated services that screen participants for eligibility for public sector benefit programs (e.g., Medicaid, SNAP, WIC, and nearly 20 other local, state, and national programs) as well as facilitating applications for those benefits.
- Campaign for Working Families (CFW) – provides free tax preparation services for families and individuals earning less than $55,000/year.

In addition to these services, participants living in intervention microclusters will also be eligible to receive a one-time $400 cash grant, which will be administered by Clarifi. The cash grant will address both potential direct and opportunity costs of working closely with partners (e.g., potential travel costs or lost wages) as well as general financial insecurity the participant and their household may be facing at baseline.

The rationale for providing these services as part of this study follows from a large literature linking economic and financial security to health and well-being.[4–6] While these services are generally available to all Philadelphians, informational and time constraints (current models of delivery require individuals to reach out to ask for services) and budgetary constraints on the partner side remain barriers to engagement. The goal of the financial intervention in this study is to increase access to these services by increasing financial capacity among the partner organizations and reducing barriers among potential beneficiaries.

The intervention group will be provided the above package of financial services using the following general approach. Within one month of enrollment and completing the baseline survey, the research team will contact intervention group participants, provide information on each of the financial partners, as well as a checklist for financial documents needed to have on hand to work with each partner. At that time, intervention group participants will select a pre-filled appointment slot with the Clarifi team for their initial intake. This appointment can either be in-person or virtual, depending on the participant's preference. Intervention group participants will receive text-message reminders in advance of their initial appointment, as well as a follow up text to assess whether they attended the appointment after the intended date and time. In the event participants were unable to participate, the research team will reschedule the initial session and again confirm participation via text-message. Participants will be eligible to receive their one-time $400 at this initial session, which will be delivered in the form of a check or direct deposit based on participant preference. After this initial meeting, the

research team will help participants schedule a second appointment (and any subsequent appointments, as needed), following the same strategy.

After connecting participants with the Clarifi team, participants will then be directly connected to BDT and CFW using a similar approach. BDT provides a screening tool that determines which benefits individuals are eligible for. The CC team will set up a time based on the participants' availability to complete this screening process with them in person. the participants have completed the screening process, they will call the phone line that BDT created for our study where a BDT representative will then walk the participants through the application process for benefits.

CFW provides both virtual and in-person (at several dedicated locations in the city) tax preparation services. Participation in these services will be confirmed in the same manner as the Clarifi services with the CC providing pre-selected appointment slots to the participants.

By the end of the intervention period in August 2024, the goal of the financial intervention will be for intervention group participants to have worked with a Clarifi counsellor at least 2 times and to have received a one time $400 cash grant, completed the benefits screening, application and follow-up process with BDT one time, and filed income taxes with CFW.

At the end of the intervention period, participants in the control group will receive a list comprising of each of the financial partners and their contact information, but will not receive the further engagement and support to enroll in these services; nor will they receive the $400 cash grant. Provision of information to this group goes one step beyond current outreach efforts by the financial partners, which include direct mailers and advertising.

9. Analysis plan

Outcome Measures

The primary and secondary outcomes for this study are described in detail **Table 1**. Primary outcomes will be drawn from our two-wave survey of study participants (one baseline wave and one endline wave); our secondary outcomes will be drawn from the same survey as well as from key administrative data sources (detailed in **Table 1**).

Our two primary outcomes will focus on (1) overall health and (2) psychological distress. Our measure of overall health comes from an index based on responses to three survey questions: a self-reported rating of the participant's general health (on a 5 point Likert scale, ranging from poor to excellent); the self-reported number of days in the last 30 in which poor physical or mental health precluded engagement in the participant's usual activities; and a self-reported rating change in overall health outcomes over the last 12 months (three point scale denoting worse, same, or better). We will use the method of Anderson (2008) to create a single (standardized) index of overall health.[7] This method uses the inverse covariance matrix of the variables to create the index and allows for missing observations.

Our measure of psychological distress is the Kessler-6 scale, a validated measure of non-specific psychological distress represented by the summed score of six questions querying the frequency of symptoms of feeling nervous, hopeless, depressed, restless, depressed, that everything was an effort, and worthless over the past 30 days.[8] The Kessler-6 ranges from 0-24.

Secondary child health outcomes

In addition to the outcomes listed above, we plan to evaluate a series of secondary outcomes focused on child health and well-being, derived from a follow-up survey administered to participants with children ages 3 to 17

at the time of 24-month follow-up. These will include caregiver-reported child health, health care utilization, and several outcomes related to child well-being, neighborhood safety for children, and parenting, as listed in Table 2.

We will also examine additional child health outcomes for all children residing in IGNITE study clusters using secondary analysis of existing data sets. Specifically, we will assess school attendance and performance for all cluster residents using Philadelphia school district data, birth outcomes for cluster residents using Pennsylvania birth certificate data, and health care utilization outcomes for all cluster residents using electronic health record data from the Children's Hospital of Philadelphia. These outcomes are also included in Table 2. We will obtain separate approval from the Children's Hospital of Philadelphia Institutional Review Board prior to abstraction of electronic health record data for these child health outcomes.

Power Calculations

For this cluster randomized trial, we assume a Type I error rate of 0.05 and a desired power of 0.8 for the primary outcomes. Our study will include 60 microclusters (30 intervention, 30 control) with at least 8 participants in each cluster (n=480 across all clusters). We will have no fewer than 480 and can enroll up to 720. The number of participants enrolled will depend on our dynamic enrollment strategy that we've discussed already. We assume an intraclass correlation (ICC) of 0.05. For our primary outcomes (and all survey-based outcomes), we will fit a marginal model using generalized estimating equations (GEE) to estimate the effect of the intervention relative to control. Under these assumptions, we will be able to detect an intervention effect of 0.33 s.d at 80% power with 30microclusters per arm (60 total) and 8 participants per microcluster.[9] This is a conservative estimate of power since we will adjust for the baseline value of the outcome and other covariates associated with the outcome. If we are only able to sample from 50 microclusters (25 per arm; n=400 across all clusters), we will be able to detect a moderate effect size of 0.37 s.d. at 80% power. Assuming up to 25% attrition between baseline and endline, we would still be able to detect a treatment effect of 0.31 s.d.

Statistical Analysis

Individual-level primary and secondary outcomes

For all primary and secondary outcomes drawn from our two-wave survey of 720 trial participants, we will assess differences in outcomes between the intervention and comparison groups using Generalized Estimating Equation models (GEE) that account for clustering at the study microcluster level. We will use canonical link functions for all outcomes. All models will adjust for the baseline level of the outcome, all microcluster-level characteristics used in the covariate constrained randomization (see randomization protocol),[10] any individual characteristics found to be imbalanced between the intervention and control groups at baseline.

We will conduct an intention-to-treat analysis: participants that move out of (or across) study clusters, separately engage with community partner services while in the control group, or do not engage with these services while in the treatment group will all be considered exposed to their original treatment assignment.

Given that our study includes two primary outcomes, we will address for simultaneous inference using a stacked GEE approach.[11] This approach adequately covers family-wise Type I errors in a manner that is more efficient than overly conservative approaches such as Bonferroni-Holm.

We will use a similar set of approaches for the survey-based secondary outcomes. For these outcomes we will report both unadjusted p-values as well as p-values adjusted for multiple inference (again based on models using a stacked GEE approach).

Will conduct four sensitivity analyses. First, we will assess for non-random attrition by regressing a binary indicator for each participant equal to 1 if the participant did not complete a follow-up survey on the treatment indicator, microcluster level attributes used in the covariate constrained randomization procedure, and any individual-level covariates that were not balanced at baseline (adjusting standard errors for clustering at the microcluster level). In the event of non-random attrition (denoted by a statistically significant coefficient on the treatment indicator from the above regression), we will use inverse probability weighing approaches (IPW) to address potential biases. We will also use an alternate strategy that calculates the lower bound of treatment effects by assigning the "best" (i.e., most positive) sample value of an outcome to attritors in the control group and "worst" sample value of an outcome to attritors in the treatment group.[12]

Second, we will estimate models that additionally include binary indicators denoting any CC who conducted interviews and fostered linkages with financial partners for each participant. Third, we will estimate a permutation inference model in which we will run our GEE models without covariates in 1,000 permutations, each of which represents a model in which treatment assignment is randomly assigned (or shuffled) 1:1 at the microcluster level (95% CIs for this method, which does not assume a specific error structure, will be constructed a the interval of estimates ranging from the 2.55^{th} to the 97.5^{th} percentile of the distribution of 1,000 point estimates).[13] We will compare estimates from our main models to estimates from these uncontrolled models. Differences would suggest potential unobserved confounding. In the event of substantive differences, we will estimate bounds on the ITT effects.[14] Fourth in the event of prevalent (e.g., greater than 20%) non-adherence to the intervention, we will estimate average treatment on the treated (ATT) parameters to recover causal effects of full participation in the intervention on the outcomes.[15] (Given that the place-based interventions will occur without direct involvement of trial participants, non-adherence in this case would most likely to apply to the financial interventions.)

Microcluster level secondary outcomes

For secondary outcomes based on microcluster-level administrative data, we will use a difference-in-differences strategy, which leverages additional power from repeat (quarterly) observations that are available in administrative data.[16] Specifically, we will estimate a Poisson-fixed effects model for each secondary outcome on the interaction between binary indicators for calendar time (quarter-year) and binary indicator of intervention status, adjusting for cluster and calendar time (quarter-year) fixed effects (the cluster fixed effect subsumes the main effect for treatment status); microcluster populations at baseline will be used as the exposure terms. This approach is known as an event study specification.[17] The time period of analysis will comprise the 8 quarters prior to intervention and all quarters over the course of the intervention period, which comprises the duration between the end of enrollment and baseline survey data collection to the beginning of follow-up data collection, and the post-intervention period, which all quarters between the beginning and end of follow-up survey data collection. (As data becomes available, we will, in the future, also conduct separate analysis that includes periods 8 quarters after the end of survey data collection, once these data become available. This analysis will be viewed as an extension of our primary difference-in-differences model to assess whether treatment effects were sustained after intervention period ended.)

The coefficients on the terms interacting treatment status with time periods prior to the intervention serve as visual and statistical checks of the parallel trends assumption, which we expect to hold given the randomized selection of intervention and control groups. However, to address potential failures of the parallel trends assumption, we will conduct a specification test in which we will estimate and trend out of the post-intervention period any differential pre-intervention trends in outcomes between the two groups.[17] The coefficients on the terms interacting treatment status with time periods after the intervention period will recover the overall (dynamic) intervention effect.

In addition to this "event study specification," we will also estimate a standard difference-in-differences model in which the calendar time × × treatment interactions are replaced by intervention period ×× treatment interaction and a post-intervention period ×× treatment interaction. These two terms will capture average intervention impacts during intervention implementation and immediately thereafter, with the latter being the treatment effect of interest.

For all models, we will adjust standard errors for clustering at the study microcluster level. We will report both unadjusted and multiple-comparisons adjusted[18] p-values for all outcomes.

Sub-group analyses

For our primary outcomes and survey-derived secondary outcomes, we will estimate the above GEE models separately for the following subgroups:

- Gender (persons identifying as men vs. persons identifying as women; if the sample size permits, we will also consider separate models for trans- and non-binary individuals)
- Level of education (split by the sample median years of schooling)
- Age (over 50 versus under 50)

We will assess statistical differences in treatment effects between categories within each subgroup by estimating versions of our main GEE models that fully interact all terms with the binary subgroup indicator, and assessing the standard error and 95% CI on the interaction between treatment and the subgroup indicator.

Evaluating Mechanisms

In addition to evaluating treatment effects on secondary outcomes, we will assess potential mechanisms underlying intervention effects on the primary outcomes using three *descriptive* (and exploratory) approaches.

First, we will use our survey data to examine the extent to which the non-health secondary outcomes (e.g., food security, financial security, social cohesion, stress, experiences of racism, exposure to crime, engagement with greenspaces, health care utilization) mediate the relationship between the intervention and any impacts on the primary outcomes. Specifically, we will conduct a causal mediation analysis to decompose intervention effects by each set of potential mediators. Our method will follow the strategy of Heckman et al (2013), who use an ordinary least squares based approach.[19]

Second, we will assess changes in key process measures, namely aggregate information on participation in specific social programs, tax returns and refunds, and credit scores. Per agreement with the community financial organizations partnering on this study, this information would only be available at the aggregate level for the treatment group. However, the degree of engagement in different financial services can help assess which services may have been more important in driving intervention effects. For example, if participants in the treatment group on average received large tax refunds, but did not sign up for new benefit programs, that would implicate the former as a potential mechanism (though without information counterfactual changes in the outcome in the control group, this cannot be proven).

Third, we will assess whether estimated intervention effects were larger among individuals who were most likely to benefit from different program components. For example, individuals who at baseline were not accessing major public benefits or who had not filed tax returns prior would be more likely to benefit from financial interventions than those already engaged with these activities. Similarly, individuals living in study clusters with relatively larger numbers of abandoned lots, fewer trees, or more abandoned homes would stand to benefit more from the environmental interventions than those who did not. Formally, we will estimate versions of our main GEE models for the primary outcomes in which we will include interactions between the treatment indicator and binary indicators for individuals participating in fewer than sample median number of public

benefit programs; not filing (or had someone file on their behalf) a tax return in the previous year; being below the median of the household financial security scale; living in a microcluster below the median in terms of tree canopy; living in a microcluster that is above the median in terms of the number of abandoned lots; and living in a microcluster that is above the median in terms of the number of houses. Positive and statistically significant coefficients on these interaction terms would provide suggestive evidence that the specific intervention that would address the pre-intervention attribute in question helped drive treatment effects. For example, a positive and significant coefficient on the interaction between treatment and living in a cluster with above the median numbers of abandoned lots would suggest that abandoned lot remediation played a role in driving overall treatment effects. Interpretation of these coefficients requires knowledge of actual exposure to treatments; e.g., it would be more credible to conclude that provision of tax preparation services helped drive health outcomes if large numbers of intervention group participants reported using these services.

Table 1. Primary and Secondary Outcome Measures

Primary Outcomes				
Outcome	**Measure**	**Data Source**	**Type of Data**	**Timeframe**
Overall Health Index	Composite index using method of Anderson (2008) based on three questions: rating of overall health (5-pt Likert ranging from poor to excellent); rating of how health has changed in last 6 months (better, same, worse); and number of days in the last 30 where physical or mental health precluded engagement in usual activities (self-care, work, recreation); (Oregon HIE)	Survey	Continuous (index)	Baseline, 24 months
Psychological distress	Kessler-6	Survey	Continuous (scale)	Baseline, 24 months
Secondary Outcomes				
Outcome (by domain)	**Measure**	**Data Source**	**Type of Data**	**Timeframe**
Health				
Overall health	Rating of overall health (5-pt Likert ranging from poor to excellent) (Oregon HIE)	Survey	Ordinal (poor, fair, good, very good, excellent)	Baseline, 24 months
Poor health	Whether individual reported either poor or fair health to overall health question (Oregon HIE)	Survey	Binary (1 = poor or fair health)	Baseline, 24 months
Change in overall health	Rating of how health has changed in last 6 months (better, same, worse)	Survey	Ordinal (better, same, worse)	Baseline, 24 months
Healthy days	number of days in the last 30 where physical or mental health precluded engagement in usual activities (self-care, work, recreation)	Survey	Continuous (number of days)	Baseline, 24 months
Sleep duration	Number of hours of usual sleep (BRFSS)	Survey	Continuous (number of houses)	Baseline, 24 months

Short sleep	Less than seven hours of usual night sleep (BRFSS)	Survey	Binary (1 = short sleep)	
Health care access and utilization				
Healthcare access	Received all needed care in the last 6 months (BRFSS)	Survey	Binary (1 = received all needed care)	Baseline, 24 months
Finances and Benefit Program Participation				
Financial well-being	Consumer Financial Protection Bureau, Abbreviated Financial Well-being Survey	Survey	Continuous (scale)	Baseline, 24 months
Food insecurity	Current Population Survey Food Security Supplement Screener	Survey	Continuous (scale)	Baseline, 24 months
Income tax filing	Whether or not individual (or someone in household on behalf of individual) filed previous years income tax (yes, planning to file late, no) (internally developed)	Survey	Binary (1 = yes)	Baseline, 24 months
Home ownership	Whether or not individual owns house, condo, or mobile home (Add Health)	Survey	Binary (1 = yes)	Baseline, 24 months
Owing on mortgage	Whether or not individual has remaining mortgage payments (internally developed)	Survey	Binary (1 = yes)	Baseline, 24 months
Total debt	Amount of debt added altogether, not including mortgage. (Add Health)	Survey	Continuous (scale)	Baseline, 24 months
Participation in public medical benefit programs	Participation of a household member (including respondent) in Medicaid, Medicare, Medicare savings, LIS, CHIP, Qualified Health Plans, SelectPlan, other, or none (internally developed)	Survey	Binary indicators for participating in any program (=1) and separate indicators for participating in each program (=1)	Baseline, 24 months
Participation in public food benefit programs	Participation of a household member (including respondent) in SNAP, WIC, Senior Food Box, other, or none (internally developed)	Survey	Binary indicators for participating in any program (=1) and separate indicators for participating in each program (=1)	Baseline, 24 months

Participation in public income support or cash benefit programs	Participation of a household member (including respondent) in TANF, LIHEAP, SSI/SSDI, UI, PA General Assistance, PA Emergency Rental Assistance, EITC, CTC Refugee Cash Assistance, CCIS, PA Child Care Tax Credit, other, or none (internally developed)	Survey	Binary indicators for participating in any program (=1) and separate indicators for participating in each program (=1)	Baseline, 24 months
Participation in public home ownership benefit programs	Participation of a household member (including respondent) in PTRR, Homestead Exemption, LOOP, Basic Systems Repair Program, PA Homeowner Assistance, Phily First Home Program, Philadelphia Home Repair Assistance, other or none (internally developed)	Survey	Binary indicators for participating in any program (=1) and separate indicators for participating in each program (=1)	Baseline, 24 months
Greenspaces and Trees				
Frequency of greenspace engagement	Frequency with which individual visits a greenspace (such as a park, garden, greened vacant lot, trail, or any other outdoor space with vegetation) (adapted from Evenson et al 2013 Environment and Behavior)	Survey	Ordinal (never, rarely, once a month, few times a month, once a week, few times a week, every day)	Baseline, 24 months
Time spent in greenspace	Time spent in a greenspace on a typical day (adapted from Evenson et al 2013 Environment and Behavior))	Survey	Ordinal (30 min or less, 31-60 min, 1-2 hrs, 2+ hrs)	Baseline, 24 months
Reasons for not spending time in greenspace	Things that stop an individual from spending time in greenspace (adapted from Evenson et al 2013 Environment and Behavior)	Survey	Categorical (weather (too cold or too hot), safety concerns, no time, too tired, I don't like spending time outside, other, nothing stops me from spending time outside in greenspace)	Baseline, 24 months
Perception of tree cover	Beliefs about number of trees in the neighborhood (internally developed)	Survey	Categorical (need more trees, enough trees, need less ttrees, unsure)	Baseline, 24 months

Tree planting concerns	Whether or not individual has concerns about planting more trees in neighborhood (internally developed)	Survey	Binary indicators for any concerns (=1)	Baseline, 24 months
Perceived tree health benefits	Whether or not individual believes trees confer health benefits (e.g., safety, mental health benefits, physical health benefits, social benefits, environmental benefits, aesthetic benefits)	Survey	Binary indicators denoting belief of any health benefits (=1) and separate indicators for each type of benefit	Baseline, 24 months
Stress and Agency				
Perceived stress	Perceived Stress Scale	Survey	Continuous (scale)	Baseline, 24 months
Neighborhood Perceptions				
Time spent in neighborhood	If individual endorses spending time relaxing, socializing, or hanging out in porches, stoops, and front yards of neighborhoods (adapted from Kahneman et al 2004 Science)	Survey	Continuous (scale)	Baseline, 24 months
Neighborhood social capital	Neighborhood Social Cohesion & Exchange and Social & Physical Disorder Scales	Survey	Continuous (scales)	Baseline, 24 months
Physical disorder	Whether or not participant reports a lot of abandoned buildings in their neighborhood (Ross and Mirowksi)	Survey	Binary (1 = yes)	Baseline, 24 months
Microcluster-Level Outcomes				
Neighborhood crime rates	Number of violent crimes, serious crimes	Philadelphia Police Dept. Crime Data - open access	Continuous (rate)	Quarterly data from 8 quarters prior to enrollment and 4 quarters after intervention period complete
Nuisance calls	Number of 311 calls	City of Philadelphia - open access data	Continuous (rate)	Quarterly data from 8 quarters prior to enrollment and 4 quarters after intervention period complete

Table 2. Child Health Outcome Measures

Secondary Child Health Outcomes

Outcome (by domain)	Measure	Data Source	Type of Data	Timeframe
Health				
Caregiver-Reported Child Health Composite Score	Child Health Questionnaire-28 (CHQ-28) Composite Score (Includes a series of questions focused on overall child health, activity limitation, emotional/behavioral difficulties, mood, relationships, and family cohesion)	Survey	Continuous (composite score)	24 months
Caregiver-Reported Child Health	Rating of child health on a 5-point Likert scale, ranking from poor to excellent (CHQ-28)	Survey	Ordinal (poor, fair, good, very good, excellent)	24 months
Health Care Utilization				
Well child care use	Caregiver report of number of well child visits in the preceding 12 months (National Survey of Children's Health)	Survey	Continuous (number of visits)	24 months
Sick clinic visits	Caregiver report of number of sick clinic visits in the preceding 12 months (National Survey of Children's Health)	Survey	Continuous (number of visits)	24 months
Emergency room visits	Caregiver report of number of emergency room visits in the preceding 12 months (National Survey of Children's Health)	Survey	Continuous (number of visits)	24 months
Hospitalizations	Caregiver report of number of hospitalizations in the preceding 12 months (National Survey of Children's Health)	Survey	Continuous (number of visits)	24 months
Usual source of care	Caregiver report of whether the child has a usual source of care (National Survey of Children's Health)	Survey	Binary (1 = yes)	24 months
Forgone health care	Caregiver report of whether child needed but did not receive medical, mental health, dental, or vision care in the previous 12 months (National Survey of Children's Health)	Survey	Binary (1 = yes)	24 months
Difficulty paying medical bills	Caregiver report of difficulty paying medical bills in the previous 12 months (National Survey of Children's Health)	Survey	Binary (1 = yes)	24 months
Uninsurance or gaps in insurance in previous 12 months	Caregiver report of uninsurance or gaps in insurance in the previous 12 months (National Survey of Children's Health)	Survey	Binary (1 = yes)	24 months
Child Well-Being				
Average sleep duration	Caregiver report of child's average sleep duration in the previous week (National Survey of Children's Health)	Survey	Categorical (Less than 7 hours, 7 hours, 8 hours, 9 hours, 10 hours, 11 hours, 12 or more hours)	24 months
Time spent playing outdoors on weekdays	Caregiver report of child's time spent playing outdoors on weekdays (National Survey of Children's Health)	Survey	Categorical (Less than 1 hour, 1 hour, 2 hours, 3 hours, 4 or more hours)	24 months

Time spent playing outdoors on weekends	Caregiver report of child's time spent playing outdoors on weekends (National Survey of Children's Health)	Survey	Categorical (Less than 1 hour, 1 hour, 2 hours, 3 hours, 4 or more hours)	24 months
Screen time	Caregiver report of child's time spent in front of a TV, computer, or other electronic device (National Survey of Children's Health)	Survey	Categorical (Less than 1 hour, 1 hour, 2 hours, 3 hours, 4 or more hours)	24 months
Neighborhood safety for children				
Neighbors watch out for children	Caregiver agreement with the statement, "We watch out for each other's children in this neighborhood" (National Survey of Children's Health)	Survey	Categorical (Definitely agree, somewhat agree, somewhat disagree, definitely disagree)	24 months
Child safety in neighborhood	Caregiver agreement with the statement, "This child is safe in our neighborhood" (National Survey of Children's Health)	Survey	Categorical (Definitely agree, somewhat agree, somewhat disagree, definitely disagree)	24 months
Parenting				
Difficulty caring for child	Caregiver report of how often they feel their child is difficult to care for (National Survey of Children's Health)	Survey	Categorical (never, rarely, sometimes, usually, always)	24 months
Bothered by child	Caregiver report of how often they feel their child does things that bother them a lot (National Survey of Children's Health)	Survey	Categorical (never, rarely, sometimes, usually, always)	24 months
Angry with child	Caregiver report of how often they feel angry with their child (National Survey of Children's Health)	Survey	Categorical (never, rarely, sometimes, usually, always)	24 months
Coping with child raising	Caregiver-self report of how they are handling the day-to-day demands of raising children (National Survey of Children's Health)	Survey	Categorical (Very well, somewhat well, not very well, not well at all)	24 months
Microcluster-level child health outcomes				
School attendance	Proportion of school days attended	Philadelphia School District Data	Continuous	Annual data from 2 years prior to enrollment through 1 year after

				intervention period complete
School performance	Grade point average	Philadelphia School District Data	Continuous	Annual data from 2 years prior to enrollment through 1 year after intervention period complete
Preterm birth	Rate of preterm birth (birth < 37 weeks gestational age)	Pennsylvania birth certificate data	Continuous (rate)	Quarterly data from 8 quarters prior to enrollment and 4 quarters after intervention period complete
Low birth weight	Rate of low birthweight (birthweight < 2000 grams)	Pennsylvania birth certificate data	Continuous (rate)	Quarterly data from 8 quarters prior to enrollment and 4 quarters after intervention period complete
Emergency room utilization	Emergency room visits in the previous 12 months	Children's Hospital of Philadelphia Electronic Health Record	Continuous (rate)	Annual data from 2 years prior to enrollment through 1 year after intervention period complete
Hospitalization	Number of hospitalizations in the previous 12 months	Children's Hospital of Philadelphia Electronic Health Record	Continuous (rate)	Annual data from 2 years prior to enrollment through 1 year after intervention period complete

Qualitative Analysis

We will use an applied thematic analytic approach to qualitative data analysis. Data analysis will coincide with data collection, enabling us to adjust data collection procedures to capture emerging and unexpected phenomena. Starting with the first 3-5 interviews, qualitative data will be coded in cycles by the coding team, led by Dr. Lane-Fall and performed by the Penn Mixed Methods Research Laboratory. The first cycle of coding will enable generation of a codebook grounded in the data (de novo codes) and in a priori codes reflecting CFIR, the Health Equity Implementation Framework, and our knowledge about the interventions. During successive coding cycles, we will refine the codebook to reflect emerging themes and recode data as needed using a constant comparative approach. Although we will use consensus coding to ensure consistency in the analytic process, we will double code a subset of the transcripts to enable calculation of interrater reliability. We will use interrater reliability, in turn, to recalibrate the coding process as needed. We will use NVivo qualitative analysis software (QSR International, Doncaster, Victoria) to manage transcripts and to undertake analysis. Although the interview analysis is primarily qualitative, we will seek out ways to mix qualitative and quantitative data in meaningful ways, e.g., interview findings may prompt additional quantitative analyses to elucidate relationships between measures thought to be unrelated. Finally, because qualitative interviews will begin during the intervention period and analyzed in real time, we will specifically evaluate for perceived worsening of disparities or inequities to ensure we are not causing harm.

10. Investigators

Eugenia South, MD and Atheendar Venkataramani, MD, PhD are lead Principal Investigators

11. Human research protection

11.1 Data confidentiality

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study. Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords. Wherever feasible, identifiers will be removed from study-related information. Precautions are in place to ensure the data are secure by using passwords and encryption, because the research involves web-based surveys.

11.2 Subject confidentiality

All participants will provide informed consent for access to the data they generate as part of this research study. All study staff will be reminded to appreciate the confidential nature of the data collected and contained in these databases. The Penn Medicine Academic Computing Services (PMACS) will be the hub for the hardware and database infrastructure that will support the project. The PMACS is a joint effort of the University of Pennsylvania's Abramson Cancer Center, the Cardiovascular Institute, the Department of Pathology, and the Leonard Davis Institute. The PMACS provides a secure computing environment for a large volume of highly sensitive data, including clinical, genetic, socioeconomic, and financial information. Among the IT projects currently managed by PMACS are: (1) the capture and organization of complex, longitudinal clinical data via web and clinical applications portals from cancer patients enrolled in clinical trials; (2) the integration of genetic array databases and clinical data obtained from patients with cardiovascular disease; (3) computational biology and cytometry database management and analyses; (4) economic and health policy research using Medicare claims from over 40 million Medicare beneficiaries. PMACS requires all users of data or applications on PMACS servers to complete a PMACS-hosted cybersecurity awareness course annually, which stresses federal data security policies under data use agreements with the university. The curriculum includes Health Insurance Portability and Accountability Act (HIPAA) training and covers secure data transfer, passwords, computer security habits and knowledge of what constitutes misuse or inappropriate use of the server. We will implement multiple, redundant protective measures to guarantee the privacy and security of the participant data. All investigators and research staff with direct access to the identifiable data will be required to undergo annual responsible conduct of research, cybersecurity, and HIPAA certification in accordance with University of Pennsylvania regulations.

Data will be stored, managed, and analyzed on a secure, encrypted server behind the University of Pennsylvania Health System (UPHS) firewall. This server was created for projects conducted by the Urban Health Lab. All study personnel that will use this data are listed on the IRB application and have completed training in HIPAA standards and the CITI human subjects research. Data access will be password protected. Whenever possible, data will be de-identified for analysis.

11.3 Subject privacy

Participation will be kept confidential. Data are being collected specifically for research purposes and will be managed by the PIs and study team. Subject identifier paperwork includes contact list with name, street address, telephone number, possibly email (depending on participants preferred method of contact), up to 2 contact people, and full consent forms. We will inform participants that we are collecting this information in order to

contact participants. No people outside the study team will have access to this information. This information will be linked to a study ID.

Data will be transferred via a firewall-protected, secure, electronic file-transfer to computer server space dedicated to the proposed study. Only MPIs Drs. South and Venkataramani will have master access to this server. Co-investigators, project managers, research coordinators, and research assistants will be granted data access at the discretion of the MPIs. Any paper-based records (such as the informed consent and HIPAA authorization form), will be kept in a locked cabinet, inside a locked office, within a Blockley access only building on Penn's campus. All identifying information will be destroyed at the end of the study period.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify participants in any action or suit unless they say it is okay. They also cannot provide them as evidence unless participants have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

11.4 Data disclosure

The following entities, besides the members of the research team, may receive protected health information (PHI) for this research study: The Office of Human Research Protections at the University of Pennsylvania - Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. Information will also be shared with our study partners providing services for participants:

- Clarifi
- Campaign for Working Families
- Benefits Data Trust
- Pennsylvania Horticultural Society

11.5 Data safety and monitoring

The PIs will be responsible for monitoring data and safety and reporting all serious adverse events, protocol deviations/violations and unanticipated events to the IRB. A written research protocol will go through an IRB review at the University of Pennsylvania to ensure protection of the rights and welfare of human research subjects. The research team, led by the investigators, will be aware of and will monitor possible areas of risk to the research participants. Weekly team meetings will include discussion of any safety and data issues that are observed.

11.6 Risk/benefit

11.6.1 Potential study risks

There are almost no risks to from participation in this study. We will make every effort to keep personal information confidential. Participants may find it uncomfortable to answer some of the questions. They will be able to skip any question they do not feel comfortable answering or end the interview at any time.

A final risk involves the safety of our community coordinator team. Their safety is of the utmost importance so various measures are in place to minimize their risk. The community coordinators will be able to end a home visit at any time if they feel the safety of the subject or themselves is at risk, or if the subject is experiencing psychological distress.

11.6.2 Potential study benefits

Participants may possibly benefit by increasing their financial education, receiving money in their tax return, and accessing a range of benefits they were eligible for but did not previously receive. They may also benefit from an emergency cash grant. Participation could also help us better understand the impact of neighborhood environments and economic inequalities on health outcomes. Participants may get satisfaction knowing they are contributing to our understanding of racial health disparities.

11.6.3 Risk/benefit assessment

There is minimal risk of breach of data and appropriate measures have been taken. Therefore, we believe the risk/benefit assessment is favorable given the potential insights that could be yielded from the findings of this study.

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