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A multisector community-engaged collaborative for mental health integration in primary care and housing developments: Protocol for a stepped-wedge randomized controlled trial (the Harlem Strong Program)

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Abstract

Background Addressing mental health disparities following COVID-19 requires adaptive, multi-sectoral, equity-focused, and community-based approaches. Mental health task-sharing in gateway settings has been found to address mental health care gaps in low- and middle-income countries, but is not a common practice in the U.S., especially in non-medical settings, such as low-income housing developments (LIH). This research study will evaluate the effectiveness of a multisectoral community-engaged collaborative for task-sharing mental health care on consumer, provider, and implementation outcomes, as well as identify barriers and facilitators for implementation.

Methods In this stepped-wedge randomized controlled trial with technology supplementation, LIH and primary care sites will be randomly assigned to one of five sequences of three implementation strategies: (1) Education and Resources (E&R), which involves online training and resources on basic mental health task-sharing skills, (2) Multisectoral Community Collaborative Care (MCC), which consists of all E&R resources plus additional community responsive implementation supports and participation in a multisectoral coalition and (3) MCC+Technology, which combines the MCC condition resources with a community crowdsourced technology solution to support implementation. The primary outcome is the effectiveness in meeting consumers' needs through direct service (e.g., adequately addressing depression and anxiety symptoms), and through implementation to increase access to mental health care (reach). The secondary outcome examines additional consumer outcomes including health functioning and social risks, as well as implementation outcomes including provider skills, program adoption, and factors related to barriers and facilitators of quality implementation. A total of 700 consumers receiving mental health care at 20 sites will be surveyed at baseline, 6-, and 12-month follow-ups. Additionally, 100 providers will be evaluated at baseline, 6-, 12-, and 24-month follow-ups before training and after randomization.

Discussion We hypothesize that MCC and MCC+Technology conditions will demonstrate significantly higher efficacy in changing primary outcomes compared to E&R, and the MCC+Technology supplement will show significantly higher levels of reach of mental health tasks compared to the MCC condition alone. These findings will demonstrate

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the feasibility of mental health integration into accessible, non-medical community settings such as LIH. Moreover, it will help establish a multilevel system solution based on community engagement and planning with a multisectoral collaboration that can be sustained community-wide.

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Keywords Implementation science, Quality improvement, Education and resources, Collaborative care, COVID-19, Low-income housing, Primary care, Minoritized population, New York City

Background

Since the COVID-19 pandemic, depression and anxiety rates have tripled in the U.S. [1], with Black and Latino communities disproportionately affected [2, 3]. Lowincome racially and ethnically minoritized communities have experienced the most significant impacts [4], with higher rates of COVID-19 diagnosis and death than white Americans [4]. The pandemic's economic repercussions have resulted in the highest levels of unemployment since the Great Depression, with 59% of the Latino population experiencing salary reduction, job loss, or both, compared to 43% of American adults [5]. In Harlem, New York City (NYC), a predominantly Black and Latino neighborhood, nearly one-third of all households live below the federal poverty threshold [6]. The rates of unmet mental health needs in this neighborhood have worsened since COVID-19 [7, 8], owing to economic stress and health crises that affect families, businesses, and community-based organizations (CBOs), further straining an already under-resourced system. Historically, racially and ethnically minoritized groups have faced limited access and received poor quality of mental health care, mainly due to severe shortages of mental health providers with the appropriate cultural and linguistic competence, lack of evidence-based interventions evincing acceptable cultural fit [9], system fragmentation, lack of resources in community-based safety net organizations, distrust in health systems, stigma, and low mental health literacy [10-12]. To prevent widening disparities and fortify the community safety net system, we must forge a culturally responsive, equity-focused system of care that acknowledges and accounts for the effects of the historical deficit of services for these underserved communities.

Trusted, accessible community settings, such as low-income housing developments (LIH), can be ideal gate-ways for mental health integration. The provision of resources in these settings has expanded mental health service availability for underserved communities, particularly in the aftermath of COVID-19, which disproportionately devastated minoritized communities [13–19]. Racially and ethnically minoritized communities face an onslaught of syndemic factors; as a result, LIH is disproportionately populated by individuals from these groups.

Racial capitalism and other social determinants of health reduced the resources available to address COVID-19 and complicated recovery efforts. CBOs play a critical role in these settings as part of the social safety net. They often serve as the primary contact for individuals seeking care and can help bridge the gaps in the formal medical and mental healthcare systems. CBOs providing housing support may be vital in reaching the most vulnerable populations, particularly those living in LIH or newly housing insecure. Supportive housing, where behavioral health services are integrated into residential facilities, has also improved mental health outcomes for multiple populations, including residents with major mental health conditions and substance use disorders [20, 21]. Lack of housing is correlated with more frequent use of public systems, such as jails and emergency rooms, whereas unhoused people who are placed in supportive housing reduce their visits to public carceral, healthcare, and service systems, and report higher social support and fewer mental health symptoms than their peers housed in other settings [21]. Given the effectiveness of integrating mental health interventions into housing for more vulnerable populations, this approach may also be used for supporting wellness and addressing common mental health concerns like depression and anxiety. Delivering mental healthcare in LIH can potentially minimize barriers to care, such as public system mistrust and mental health stigma, as well as the daunting logistics and costs of treatment, by tapping into residential case managers who are already trusted and familiar with the community resources, context, and residents. This approach also increases access to services by reducing barriers such as childcare, transportation logistics, and cost by providing care in or close to home. Integration of mental health support tasks with other home-based social services holds the potential to facilitate consumers' access to a full spectrum of services to meet their needs, allowing them to optimize their resources, including time, energy, and finances towards their overall wellbeing. Collaborative care serves as a recommended quality improvement (QI) intervention within health system to support mental health task-sharing. In this model, a mental health clinician assists non-specialists (e.g., primary care (PC) providers) in delivering routine screening, mental health

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literacy training, research-supported treatment, selfmanagement, and care coordination [22]. This model is ideal for increasing access to mental health promotion, screening, referrals, and system navigation services, and has been found to reduce patient symptoms in several systematic reviews [23-25]. However, much of this evidence is derived from medical and/or PC settings [26-29]. Therefore, the models they deploy may not directly apply to CBOs without staff mental health providers and built-in clinical supervision and resources. Furthermore, most collaborative care interventions occur in a single setting, where the mental health specialist is located within or integrated into the PC site. Community Partners in Care (CPIC) is one of the few studies that has evaluated a multi-agency collaborative care model and found that it strengthened the community safety net by building the capacity of diverse providers in mental health support and coordination skills [30], which enhanced even non-mental health services. This community engagement approach, where a network of agencies worked together to develop an implementation plan, led to greater activation and coordination of the care system, creating "a village of care." While promising, this approach has not been replicated or evaluated in LIH, which have the additional advantage of facilitating access for a vulnerable population. Thus, an expanded community-based multisectoral collaborative care model delivered in multiple settings, and incorporating housing developments and PC sites into a collaborative network of community-based services, has the potential to address health inequities and increase linkages between health and housing developments, which is particularly important as communities recover from the COVID-19 pandemic [31].

This study aims to develop a long-lasting model for integrated mental health care in LIH and PC sites through a community-engaged, multi-level, synergistic approach to task-sharing. The goal is to address the urgent need to mitigate the manifold social, economic, and structural stressors faced by racially and ethnically minoritized communities, particularly in Harlem, NYC, who have been hit hard by COVID-19. By transforming community-based care models in response to the ongoing pandemic, this study offers an innovative solution to address the current crisis and build a more resilient and sustainable community-based healthcare and social service system. We will employ a Type II hybrid effectiveness-implementation evaluation [32] to determine the comparative effectiveness of a multisectoral community collaborative care (MCC) model and the added value of supplemental technology innovation (MCC+Technology) compared with education and resources (E&R) for mental health task-sharing, on both consumer and implementation outcomes. We hypothesize that (1) MCC and MCC+Technology models will be more effective in improving effectiveness outcomes (consumer depression and anxiety symptoms) and implementation outcomes (reach of mental health services, including receipt of counseling, mental health care navigation, and successful linkage to mental health and social services) compared to E&R; and (2) the Technology supplement will show significantly higher levels on the reach of mental health tasks compared to MCC model. Using a stepped-wedge randomized controlled trial with technology supplementation, this study seeks to (1) compare the effectiveness of implementation strategies (MCC, MCC+Technology vs. E&R) on consumer outcomes, (2) evaluate the effectiveness of the strategies on implementation and provider outcomes, and (3) explore organizational and provider barriers and facilitators related to adoption and implementation quality.

Methods

Conceptual framework

Our approach to developing a multi-system intervention is guided by Williams and Cooper's (2019) three key strategies to address health disparities [28], which are (1) creating and maintaining comprehensive "communities of opportunities" that offer resources and opportunities in the local community; (2) implementing health interventions aimed at addressing social determinants of health, and (3) conducting health promotion efforts that build community capacity to enact system change. We will also utilize community-based participatory research (CBPR) approaches [29] that have been effective in implementing mental health evidence-based interventions (EBIs) in low-resource racially and ethnically minoritized communities in previous studies [30, 33, 34].

Collaborative, participatory planning and research design

Our collaboration with Harlem Congregations for Community Improvement, Inc. (HCCI), a Harlem-based CBO, features a crucial step towards convening comprehensive communities of opportunities. HCCI, a powerful alliance of diverse faith congregations, offers a wealth of programs that empowers Harlem residents through affordable housing, community-based education, social services, health initiatives, and economic empowerment services. We will leverage HCCI alliances with other CBOs, houses of worship, elected officials and local residents to create communities of opportunities through exchange of resources and coordination of community efforts. We also partner with Healthfirst Managed Care, "New York's largest not-for-profit health insurer," which is committed to providing high-quality healthcare coverage to individuals and families in NYC. For over 25 years,

Healthfirst has been a leading force in NYC and beyond, pioneered the value-based healthcare model that rewards hospitals and physicians based on patient outcomes. Healthfirst serves over 1.8 million members and 40,000 providers, works with over 80 participating hospitals, and hosts 23 community offices throughout New York. Healthfirst contracts with 150 community-based behavioral healthcare providers throughout Harlem, and we will avail upon these relationships to support this study and increase the likelihood of sustainability for the model.

To support delivery of community mental health tasksharing, we will use several Community-Based Participatory Research (CBPR) implementation strategies to promote cultural congruence and community engagement, including (a) Community Advisory Board (CAB), (b) Community Stakeholder Planning Council (CSPC), (c) Learning Collaborative (LC), and a Collaborative Network consisting of a wide range of CBOs, faith-based organizations, behavioral health organizations, government partners, and other stakeholders to support the implementation of MCC. These community engagements will target barriers at the organizational, community, and societal levels to ensure optimal impact on outcomes across dimensions of analysis. To increase acceptability and engagement, we relied upon community stakeholders from the CAB and CSPC to develop the model of care and community implementation plans, which were created from feedback and suggestions offered by the CAB and a series of 10 CSPC meetings in the first year of the project. The Learning Collaborative and Collaborative Network will support adopting multisectoral collaborative care model through the Collaborative Network to promote mental health awareness, provide access to online training on basic mental health support skills, facilitate linkages to community-based resources, and provide a community of opportunity to all sites. Given the high needs in Harlem, the network would be open to the public, and no one would be excluded.

Mental health task-sharing

Mental health task-sharing is a proven model for expanding access to mental health care [35, 36]. It involves training non-clinicians—in this case, community workers already working in LIH and other social service settings in Harlem—to become mental health navigators who can assess and address mental health concerns by connecting individuals to appropriate care. Specifically, Harlem Strong Program navigators deliver simplified components of mental health care, including community outreach and engagement, screening for anxiety and depression, risk assessment, providing mental health education and stress management skills, interacting with consumers in

trauma-informed, culturally responsive ways, and making warm referrals where appropriate. These navigators' co-location within housing units and local PC clinics will offer Harlem residents access to mental health education, screening, stress management support, and hyperlocal referrals. The Harlem Strong task-sharing model will also include support from other staff at each LIH site, who will assist with community outreach and linkage of residents who might benefit from additional support to their site's navigators. Navigators will also be clinically supported through ongoing coaching and participating in learning collaboratives with licensed clinicians, who will support skill development through case consultation and continuous quality improvement support to increase the model's effectiveness and sustainability.

Care components

The Harlem Strong Mental Health Task-Sharing Model will comprise six main components: Community Engagement, Screening and Risk Assessment, Mental Health Education, Stress Management Counseling, and Referrals. Community Engagement efforts will offer the program to the community in ways that are traumainformed and culturally responsive, acknowledging the mental health stigma in Harlem, as described by the CAB and CSPC. Screening and Risk Assessment will consist of administering short, standardized mental health assessments to evaluate consumers' well-being and concerns and identify appropriate resources and referrals. Consumers who report symptoms of mental health concerns outside of the scope of the navigators' training, such as mania, psychosis, substance use disorders, self-harm or suicidality, as well as those who request referrals to longer-term therapies, will be referred to licensed mental health professionals within the coalition network. Consumers who endorse only mild or moderate anxiety or depressive symptoms will be offered stress management counseling, which will consist of training in evidencebased coping skills including goal-setting, mindfulness, behavioral activation, and relationship-building and communication skills, to lay the foundation for increasing consumers' self-awareness, self-efficacy, self-kindness, and emotion regulation skills, as well as assembling their toolkit of coping skills and their capacity to maintain wellbeing cultivating healthy habits, social support and belonging. Navigators will also comprehensively assess consumers' social, legal, and medical service needs, and connect them to additional resources as needed.

Description of intervention conditions Education and Resources (E&R)

Involves online training on basic mental health tasksharing skills, such as screening, psychoeducation, stress management, and referral to mental health care. All providers across the 20 sites will have access to a community resource directory along with training on community resources. The online training will be hosted on a Learning Management System powered by Moodle 3.11+and will consist of 6 online modules, including 1) Introduction to Mental Health and Mental Health Promotion, 2) Provider Self-Care, 3) Trauma-informed Care, 4) Community Care Model, 5) Counseling Skills, and 6) Stress Management and Coping Skills. Each module consists of 2-5 pre-recorded 20-30-min videos which are supported with an implementation toolkit, consisting of a provider implementation manual, forms, and tools used in the intervention, as well as the resource directory. We recommend that consumers who endorse mild or moderate anxiety or depression via the Patient Health Questionnaire with four items [37] (PHQ-4≥3) be offered The Harlem Strong Program (Fig. 1), which includes further assessment, psychoeducation, stress management counseling, and connections to additional resources as needed. For consumers exhibiting higher levels of need, referrals will be made to mental health specialists.

Multisectoral Community Collaborative Care (MCC)

Will consist of all resources offered in E&R, as well as additional training on skills related to working in a multisectoral team, care navigation, the syndemic risks of the social determinants of health, and coordination of services related to mental health, social services, and health care. Navigators will be trained to screen for mental health, assess risks and protective factors, provide mental health education, support coping skills development, and coordinate referrals to various social services. Navigators will have access to regular coaching from clinicians,

who will support these processes and continuously adapt the resource directory to reflect navigators' requests and reports of referral experiences. The CSPC group will develop the training and implementation plan, including workshops, coaching, and Learning Collaboratives to support MCC sites. While the E&R approach increases provider knowledge, the lack of live mentorship rarely results in behavior or practice change, even among mental health specialists [38-40]. Thus, providers will receive weekly group coaching for the first six months, and regular coaching for the remaining year via Zoom from a clinical supervisor at the Center for Innovation in Mental Health. Although ongoing coaching and feedback are needed to support the adoption and fidelity of EBIs [39, 41-43], they may not be sufficient for sustaining these practices, given the complex implementation barriers. Therefore, we are also supplementing this with regular network-wide learning collaboratives with multidisciplinary teams to support continuous quality improvement and the development of a structured approach to improve care provision. Gateway sites in the MCC condition will also be invited to quarterly coalition meetings to support collective problem-solving and awareness of other community resources in Harlem, and build partnerships with other community organizations in the Harlem Strong Coalition Network.

MCC and Technology

MCC+Technology will build upon all the MCC components with the addition of the creation of technological tools to meet programmatic needs identified by gateway sites to facilitate implementation across our multisector network, supported by technologists and entrepreneurs through programs such as the Firefly Mental Health

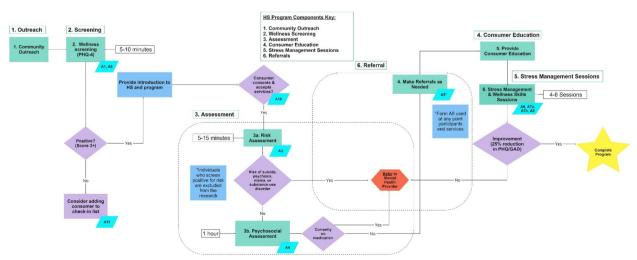


Fig. 1 Harlem Strong Program workflow

Hackathon and Accelerator programs at the City University of New York's Graduate School of Public Health and Health Policy (CUNY SPH). This component aims to generate innovative solutions that address implementation challenges for the multisectoral care system and mental health task-sharing through an online challenge competition, which is community-developed, marketable, and financially sustainable, and to test their effects on participating organizations' capacity to serve consumers. Examples of potential technology include supporting the use of a social service-oriented client management tool, using an online referral platform, creating additional resources in the Harlem Strong e-Hub, and developing a client-facing app to support wellness.

Study site characteristics and recruitment

We will partner with the LIH network and Healthfirstenrolled PC sites in Harlem to identify suitable bases for study implementation. Specifically, we will work with HCCI and Hope Community, Inc. to select 15 LIH clusters that have over 100 units, as well as staff who can implement mental health task-sharing. HCCI manages over 100 housing developments in Harlem, with 85% allocated for low-income residents, 10% affordable housing, and 5% offered at market rate. Hope Community manages 63 housing developments in East Harlem, with 305 units set aside for low-income tenants. Our team will collaborate with housing leadership to determine which sites would be most appropriate for the study (have adequate staffing and potential to integrate a care navigator) and select 15 clusters, of which ten will be from HCCI and five from Hope Community. For PC sites, Healthfirst, "New York's largest non-profit health insurer," will approach directors of all 16 PC centers in Harlem and facilitate the enrollment of five PC sites into the study. Both housing and PC sites will be considered mental health gateway sites and will be randomized into MCC or E&R at the outset of the study.

Provider recruitment

During the gateway site recruitment, we will host information sessions for gateway sites to describe the project goals, activities, and expectations. We also recommend the types of staff to recruit for navigators and supporter roles. We will recruit 60–100 providers across 20 study clusters, including 3–5 providers from each site, comprising 1–2 navigators and 2–3 supporters. Providers will be recruited after sites enroll in the study, but prior to site randomization. Sites may also replace providers should they drop out.

Navigators will participate in a 6-month hybrid training program that includes online learning modules, interactive webinars, and in-person workshops. Through

this training program, navigators will learn about the science of mental health, best practices for consumer engagement, evidence-based, trauma-informed strategies for providing support, the collaborative care model for mental health treatment, and all components of the mental health services, including screening, assessment, consumer education, stress management counseling, and referrals.

Supporters will begin community engagement and mental health promotion training before consumer recruitment. Supporters will participate in a 3-month hybrid training program combining online learning modules, interactive webinars, and in-person instruction. Through this training program, supporters will learn about the basics of mental health, how to engage and educate the community about mental health, and how to provide rapid screening during mental health promotion campaigns, as well as the team-based collaborative care model, and how to refer those with mental health concerns to the gateway sites.

Consumer recruitment

Community navigators will promote the program through community engagement activities as part of the LIH or PC Community Implementation Plans. This will involve various techniques such as posting about the Harlem Strong Program on building bulletin boards, social media, websites, newsletters, and holding events at community-trusted locations.

Consumers who screen positive for anxiety and/ or depression symptoms as part of screening with the PHQ-4 at gateway LIH and PC sites will be eligible to enroll in the consumer outcomes surveys and will be evaluated at three time points: baseline (within two weeks of screening positive based on the PHQ-4 and before receiving the intervention), 6-, and 12-month followups. Eligible consumers will be (1) Black and/or Latino, (2) adults aged 18-65, (3) English or Spanish speaking, (4) Harlem residents from LIH developments or receiving PC services in Harlem; and (5) scoring of at least 3 out of 12 indicating mild risk for depression and/or anxiety on the PHQ-4. Individuals identifying as having severe mental illness (e.g., psychosis, mania, substance use disorders, self-harm or active suicidality) using the Mini-International Neuropsychiatric Interview [44] will be excluded and referred to more advanced care within the network of licensed mental health providers [22].

Each of the 20 sites will aim to recruit 35 participants, totaling 700 participants, with five consumers per period excluding the transition period. Sample size would be E&R (n=200), MCC (n=300), and Tech (n=200) (Fig. 1). Recruitment processes will be congruent for both stages and all consumer participants will be screened

for enrollment into the study at LIH or PC sites. Due to higher rates of mental health concerns (35–40% reported increase in symptomatology) since COVID-19 [45], we expect to screen approximately 2,355 to enroll 700 consumers. Retention rates from our prior studies have ranged from 60% to 90%, varying with engagement and consumers' perception of the relevance of the intervention [20, 46, 47]. Given our experience during the formative phase and continued concerns regarding staffing shortages, we estimate a moderate level of participation (60%) and average attrition (40%) for the one-year follow-up, and therefore will over-enroll to obtain a one-year follow-up sample of 700 consumers.

Study design

We will use a stepped-wedge randomized controlled trial with supplementation design and a mixed-methods approach to test the implementation effectiveness on consumer- and provider-level outcomes. The hybrid trial compares the three implementation strategies for mental health task-sharing: (1) E&R, which involves online training on basic mental health task-shifting skills (e.g., community outreach, screening, assessment, psychoeducation, brief counseling, and referrals to mental health care), 2) MCC which consists of all E&R resources, along with additional coaching and community-engaged implementation supports, as well as participation in a multisectoral coalition, and 3) MCC+Technology which combines the MCC condition resources with a community crowd-sourced technology solution to support implementation.

Randomization

We will randomize the 20 pre-determined gateway clusters, derived from both LIH and PC sites, into one of five cohorts receiving distinct implementation sequences at the outset of the study (Fig. 2). The randomization process will proceed as follows: (1) each site will be assigned a unique number, with HCCI sites numbered 1–10, Hope Community sites numbered 1–5, and PC sites numbered 1–5; and (2) the data management lead (TTV) will use STATA version 17.0 to generate reproducible codes using the same seed, which will be used to randomly select 3 LIH sites, comprising two from HCCI and one from Hope Community, along with one PC, to create a cluster of four sites which will share an implementation sequence. The numbers selected in each sequence differ from those in the previous sequence.

Intervention sequences

Over four years (comprising eight 6-month measurement periods), each cluster will be engaged in the study, with a sequential cross-over to a higher level of implementation support for each cohort. Each sequence will have varying amounts of time exposed to the E&R and Technology supplementation conditions. All sequences will have two years of MCC. The sequences are as follows:

- **Sequence 1**: 2 years of MCC and 2 years of Tech supplementation
- Sequence 2: 6 months of E&R, 2 years of MCC, and 1.5 years of Tech supplementation
- Sequence 3: 1 year of E&R, 2 years of MCC, and 1 year of Tech supplementation
- Sequence 4: 1.5 years of E&R, 2 years of MCC, and 6 months of Tech supplementation
- Sequence 5: 2 years of E&R and 2 years of MCC

During the first period, four clusters (16 sites) will be assigned to the E&R condition and one cluster (four sites) to the MCC condition, which includes the E&R resources and the addition of the Multisectoral Collaborative Care model. Thus, all resources offered in E&R will be provided to all 20 sites at the beginning of the study. However, following the introduction of the MCC condition, sites will have a transitional 6-month period before data collection, to allow for the assimilation of the additional training and implementation support during their 2-year MCC period. Following their transition into the MCC condition, each cohort in MCC will receive up to two years of the Technology supplement condition (Fig. 2).

Evaluation and analysis plan

Our assessments will collect multi-level, mixed-methods data [48, 49], building on our previous studies, including CPIC [22, 34, 50]. All surveys including providers and consumers will be conducted using Research Electronic Data Capture (REDCap), a secure platform designed for research studies. Our evaluation and analysis plan aim to operationalize three domains of programmatic impact: Aim 1) Consumer outcomes (intervention effectiveness for consumers), Aim 2) Services and service provider implementation outcomes (reach of services and provider outcomes), and Aim 3) Implementation process factors (barriers and facilitators of implementation).

We will generate tables that summarize the distribution and extent of missingness of potential risk factors, including age in years, race/ethnicity, educational level, and employment status. The two primary outcomes are the PHQ-4 score and the reach of mental health services within six months. In intent to treat analysis of the PHQ-4 outcome, we will use mixed effects models [51] with the identity link function to evaluate the effect of interventions. The fixed effects include the interventions and the time effect, and the random effects include the site and repeated measures from the same consumer.

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		Y1		Y2		Y3		Y4	
		Q1-2	Q3-4	Q1-2	Q3-4	Q1-2	Q3-4	Q1-2	Q3-4
		1	2	3	4	5	6	7	8
	1		5	5	5	5	5	5	5
	2		5	5	5	5	5	5	5
	3		5	5	5	5	5	5	5
	4		5	5	5	5	5	5	5
	5	5		5	5	5	5	5	5
	6	5		5	5	5	5	5	5
	7	5		5	5	5	5	5	5
	8	5		5	5	5	5	5	5
	9	5	5		5	5	5	5	5
Sites	10	5	5		5	5	5	5	5
(clusters)	11	5	5		5	5	5	5	5
	12	5	5		5	5	5	5	5
	13	5	5	5		5	5	5	5
	14	5	5	5		5	5	5	5
	15	5	5	5		5	5	5	5
	16	5	5	5		5	5	5	5
	17	5	5	5	5		5	5	5
	18	5	5	5	5		5	5	5
	19	5	5	5	5		5	5	5
	20	5	5	5	5		5	5	5

KEY: E&R MCC MCC+Tech //ransition/

Fig. 2 Stepped-wedge randomized controlled trial randomization scheme

We will use the robust score test to assess whether these interventions significantly differ across the three conditions. For the implementation outcome (the reach), we will use generalized linear mixed models [51] with the log link to assess the impact of the interventions. Again, the robust score test will be used to assess the significance of the interventions. Sensitivity analyses will adjust for baseline covariates listed above.

For secondary outcomes at the consumer and provider levels, we will use mixed effects models described above to evaluate the continuous outcome and generalized linear mixed models to assess categorical outcomes. We will record and report all reasons for loss to follow-up and missing covariates. In secondary analysis, we will use inverse probability weighting [52, 53], to adjust for possible selection bias due to loss to follow-up and by missing covariate values, to examine the impact of these potential sources of bias on the intent to treat estimates and tests.

Outcome evaluation and analysis for AIM 1 & 2 *Power analysis*

We will enroll 35 consumers in each of the 20 sites, for a total sample size of 700 participants. In this stepped wedge design, power will be computed to test null hypotheses of no difference in consumer outcomes between the E&R, MCC, and MCC+Technology conditions. For the primary effectiveness outcome, the PHQ-4, its variance of the change in 6 months will be assumed to be 16. With a 0.025 Type I error rate, allowing for two primary outcomes and one primary comparison between three conditions for each primary outcome, we will have 80% power to detect a reduction of 1.08–1.38 points from baseline in PHQ-4 scores in the comparison between the E&R, and combined MCC and MCC+Technology conditions, assuming a loss to follow-up rate of up to 40%, and between-site intraclass correlation coefficients (ICC) as large as 0.05.

For the primary implementation outcome, reach for mental health services, we will assume the reach in the E&R condition is 30%. With a 0.025 Type 1 error rate, we will have 80% power to detect an increase of 24-30% in the comparison between E&R and MCC (that is, the reach at the MCC condition is about 54%-60%), assuming a loss to follow-up rate up to 40%, and ICC as large as 0.05. For the secondary comparison between MCC and MCC+Technology, assuming 70% reach in the MCC condition, a loss to follow-up rate up to 40%, and ICC as large as 0.05, with a 0.05 Type 1 error rate, we will have 80% power to detect a further increase of 17-22% in the reach (that is, the reach at the MCC-Tech condition is about 87-92%).

Program implementation

Every site will be asked to maintain a Harlem Strong participant registry, screening/assessment logbook, and program logbook, which were collected in the previous trial [22]. Site-level data will be collected and analyzed to determine screening rates for mental health distress (PHQ-4), and the number of new consumers screened relative to the total number of LIH residents or patients seen at the sites to provide insight into the reach of screening efforts. The program logbook will document dates of contact, and additional mental health progress measures (PHQ-9 and GAD-7) scores reported during each visit, and referrals made for additional services and their outcomes. These logs will be used to assess the care process and measure adoption (the extent to which providers trained in the program continue to implement mental health tasks up to 12 months post-baseline) and sustainment (the extent to which providers implement mental health tasks at 24 months).

Provider outcome

Using a repeated-measure design, we will administer online self-administered surveys to providers at four time points: baseline (during the study enrollment meeting, before the workshop), and at 6-, 12-, and 24-month follow-ups. The surveys, adapted from the previously used provider surveys [22, 30, 54], will assess sociodemographic characteristics (e.g., birth year, gender, education), mental health training, attitudes towards manualized mental health care interventions using the adapted Evidence-Based Practice Attitude Scale (EBPAS-15) [55], perception of the work environment's openness to implementing evidence-based practices using the Implementation Climate Scale (ICS-18) [56], and organizational readiness to change (ORIC-12) [57]. These provider and organizational characteristics will serve as covariates (e.g., organizational culture and climate) and exploratory outcomes. Providers will also be asked about their emotional distress using the PHQ-4 [37], mental health stigma with the Opening Minds Scale for Health Care Providers (OMS-HC-15) [58, 59], self-care activities (PCSC-21) [60] as well as burnout using the Maslach Burnout Inventory (MBI-9) [61].

Consumer outcomes

The consumer study will use a range of measures, including demographic information (e.g., age, gender, education, marital status), mental health symptomatology using PHQ-9 and GAD-7 [62, 63], the Primary Care Post-traumatic Stress Disorder Screen for DSM-5 (PC-PTSD-5) [64], resilient coping with the Brief Resilient Coping Scale (BRCS-4) [65], comprehensive adverse childhood experiences using the Philadelphia Adverse Childhood Experiences Survey [66], alcohol use with the Alcohol Use Disorders Identification Test (AUDIT-C) [67, 68], barriers to mental health care (BACE-30) [69], functional impairment using the World Health Organization Disability Assessment Schedule (WHO-DAS 2.0) [70], beliefs about mental health using the Mental Health Stigma Scale (MHSS-15) [71], self-efficacy using the adapted Mental Health Self Efficacy Scale (MHSES) [72], social needs with the Accountable Health Communities Health-Related Social Needs Screening Tool (AHC-HRSN) [73], social support using the Medical Outcomes Study (MOS) [74], family environment using the McMaster Family Assessment Device (FAD) [75], and client service satisfaction (CSQ) [76].

Outcome evaluation and analysis for AIM 3

We will supplement our primary quantitative analyses with analyses of qualitative feedback from administrators, supervisors, providers, and clients. To understand implementation progress, barriers, and facilitators, we will use a mixed methods approach, combining monthly implementation data with in-depth interviews conducted at sites demonstrating both high and low levels of program adoption. In Year 4, semi-structured individual interviews (n = 60) will be conducted with five stakeholders at each of high and low adaptors (one administrator, three staff, one supervisor) and five consumers from each of the three steps to understand "pain points" and factors associated with challenges for low performing sites, as well as "bright spots" and factors related to facilitators for highest performing site. Rank ordering of sites will be used to determine their assignment to each implementation strategy stepped condition (E&R, MCC, MCC+Technology) by the level of adoption and implementation quality of mental health task-shifting. By using the Consolidated Framework For Implementation Research (CFIR) [77], the interview will focus on the stakeholders' experience with training and

implementation support, perspective on the benefits and challenges of mental health task-shifting, reasons for participating in Harlem Strong activities, and recommendations to improve the program. Interviewers will review monthly implementation data from diverse sources (e.g., clinical records and training logs) to inform interview questions and craft the implementation story.

We will use a typology development approach in which quantitative findings will guide qualitative data coding [78]. For example, we anticipate developing codes for treatment responders and non-responders based on the narratives that describe reasons for program participation, dropout, use of stress management skills (behavior activation or problem-solving) to improve stress management. This mixed-method approach can generate more detailed insights regarding trajectories towards improved systems of service and quality of life and health functioning for Black and/or Latino people with mental health concerns from structurally disadvantaged neighborhoods to support the development of strategies to increase adoption of mental health task-sharing in LIH and PC [79]. To generate recommendations for services, we will review summaries of main analysis results as well as key narratives from qualitative analyses to richly describe consumer experiences and community efforts.

Ethics approval and consent to participate

This study obtained the Institutional Review Board approval from the Graduate School of Public Health and Health Policy, The City University of New York, U.S., and will be conducted in accord with APA ethical guidelines for Human Subjects Research. Before participating in the study, all participants will be asked to provide written informed consent.

Trial status

By January 2024, we successfully recruited 20 LIH and PC clusters, including 10 HCCI, five Hope Community, and five PC sites. All providers from these sites will be assessed before and after the training. We have currently recruited 62 providers, who are also participating in training on the Learning Management System platform. All 80 consumers from the initial sequence have been enrolled.

Discussion

The study proposes a novel approach to address mental health disparities in racially and ethnically minoritized communities. Specifically, our research focuses on expanding the MCC model, which was initially developed for PC sites [80, 81], to be implemented in LIH, an underutilized gateway for mental health task-sharing. This approach provides an opportunity to assess

the effectiveness of integrating mental health services into an untapped yet promising and accessible community setting. By leveraging this model, we can enhance access to quality mental health care for racially and ethnically minoritized communities, promote task-sharing, and enhance trauma-informed approaches and cultural responsiveness among healthcare and lay providers. Additionally, this approach may result in cost savings and increased access to care in underserved community settings.

To supplement the implementation of the MCC model in LIH, the study will adapt the quality improvement collaboratives (QICs) for community-based settings. QICs usually involve in-person learning sessions and support using Plan-Do-Study-Act models, multidisciplinary QI teams, and new data collection as part of the QI process [82]. Reviews suggest positive effects for QICs at the provider and organizational levels but mixed findings on consumer outcomes. Few rigorous studies have compared QICs to other active implementation strategies and evaluated consumer outcomes [67, 68]. Thus, this study offers a chance to compare the effectiveness of QICs (e.g., the MCC model) against other implementation models (E&R, MCC + Technology Supplement) where outcomes are assessed at both the provider and consumer levels [82-85].

The focus of this study on creating a localized community of opportunity in Harlem is a crucial step in addressing mental health disparities and increasing access to resources for a community facing multiple dimensions of structural oppression. The compounding effects of racial capitalism and other social determinants of health have concentrated neighborhood-based risk in Harlem, as it often is in racially and ethnically minoritized communities. In particular, the poverty rate in Harlem is notably high, with over 20% of households struggling below the federal poverty line [6]. Historically, Harlem has been underserved, facing significant gaps in access to healthcare and mental health services. For example, between 8% and 20% of residents do not have health insurance, and between 11% and 26% of residents forgo necessary medical care [86, 87]. These socioeconomic disadvantages are marks of expansive health disparities in the community. By creating a community of opportunity in Harlem, we can address these disparities and improve access to critical resources such as mental healthcare.

While mental health task-shifting in PC is not innovative, this study combines community engagement and intervention mapping, system science, CBPR, and planning with a multi-sectoral collaborative which rarely involves PC practices, as well as implementation in less-studied settings, such as housing. This comprehensive approach allows us to draw from multiple traditions

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to more systematically and effectively adapt and codesign Harlem Strong to community needs, and more effectively ameliorate the syndemics of the structural and social determinants of health and their impacts on community resources available to support responses to COVID-19 and mental health concerns, while creating a multi-level system solution that can be adopted and sustained community-wide. The inclusion of Healthfirst, a managed care organization, as key collaborator in the model design, also facilitates cross-site learning and development of a model that has potential to be financed and adopted by a national managed care organization. By fostering a sense of community ownership and engagement, this approach holds promise as an avenue to achieving sustained improvements in health outcomes and addressing mental health disparities in systematically disadvantaged communities like Harlem.

The proposed study faces several challenges, including the logistical complexity of conducting a large-scale stepped-wedge randomized trial in both LIH and PC settings. However, these challenges can be addressed through close collaboration with HCCI and other community partners who have co-led the formulation of this program. Another potential concern is the ability to maintain contact with LIH residents to complete follow-up survey forms. To address this issue, we plan to establish strong partnerships with LIH staff and engage community health workers to facilitate survey administration. We will also leverage technology to streamline the survey process, such as implementing electronic surveys on REDCap and providing participant reminders. Moreover, we will incentivize participation to increase response rates and ensure the sample's representativeness. By taking these measures, we aim to minimize the impact of this concern on the study outcomes.

Abbreviations

CAB Community Advisory Board CBC Community-based Care CBO Community-based Organization **CBPR** Community-based Participatory Research **CFIR** Consolidated Framework for Implementation Research

CSPC Community Stakeholder Planning Council

CUNY SPH City University of New York's Graduate School of Public Health

and Health Policy

F&R Education and Resources **EBIs** Evidence-based Interventions

Harlem Congregations for Community Improvement, Inc. HCCI

ICFR Incremental Cost-Effectiveness Ratio LIH Low-income Housing Developments

10 Learning Collaborative

MCC Multisectoral Community Collaborative Care

NYC New York City

PHO Patient Health Questionnaire

PC Primary Care OI Quality Improvement

Quality Improvement Collaboratives OIC **RFDCap** Research Electronic Data Capture

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Authors' contributions

VKN contributed to the conceptualization, design, and writing of the original protocol. TTV and VKN drafted the initial versions of this manuscript. JAF designed the learning management system. TTV leads data management and analysis, with VKN and TTV jointly contributing to data interpretation. KW and XZ conducted the power analysis write-up. VKN, TTV, DL, MAP and MRW are engaged in the trial's implementation. All authors provided feedback on and revised the previous versions of the manuscript. Finally, all authors reviewed and approved the final manuscript.

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Availability of data and materials

Data collection for this study is still in progress, thus data and materials are not yet available.

Declarations

Ethics approval and consent to participate

This study obtained the Institutional Review Board approval from the Graduate School of Public Health and Health Policy, The City University of New York, U.S., and will be conducted in accord with APA ethical guidelines for Human Subjects Research. Before participating in the study, all participants will be asked to provide written informed consent.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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