Study Protocol

Collaborative Care to Reduce Depression and Increase Cancer Screening among Low-Income Urban Women

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CLINICAL DIRECTORS NETWORK, INC.

Collaborative Care to Reduce Depression and Increase Cancer Screening among Low-Income Urban Women – Prevention Care Manager 3 Project

PROJECT PROTOCOL FOR THE RANDOMIZED CONTROLLED TRIAL (RCT)

A. STUDY PURPOSE AND RATIONALE

The Bronx, a borough of New York City, is home to 1.39 million people and is the poorest urban county in the U.S. Twenty-nine percent of the population lives below the poverty line, and 30% of individuals have not completed high school or received their GED.[1] Forty-three percent of the population is black and 54% of residents are Hispanic; 45% of the population speaks Spanish at home, and one-third of residents self-identify as foreign born.[1] Forty-two percent of individuals are enrolled in Medicaid;[2] at the same time, 18% of the population remains uninsured.[3] Almost one-third (28%) of individuals in the Bronx consider themselves to be in fair or poor health, and the Bronx was ranked the worst county in New York State with respect to population health outcomes.[4] Yet despite the numerous socio-economic and health challenges faced by its residents, the Bronx is a resilient community with a long history of community engagement.[5] In the past 25 years, non-profit housing development corporations, settlement houses, and social service agencies have come together with residents to rebuild the Bronx and to meet the social service needs of individuals and families. A number of federally qualified health centers now exist to address the healthcare needs of the community, regardless of an individual's ability to pay or immigration status. While these efforts have accomplished a great deal, more work is still needed to improve health outcomes and patients' experiences in care.

Two health-specific areas that have been identified by Bronx social and medical service providers as being of significant importance for the improvement of patient health outcomes and well-being are mental health care and cancer screening.[6] Cancer is the leading cause of premature death in the Bronx, with lung, prostate, and colorectal cancers accounting for the highest mortality among men, and lung, breast, and colorectal cancers accounting for the highest mortality among women.[7,3] The death rate due to cancer is 15% higher in the Bronx than in New York City as a whole,[3] and the cervical cancer rate in the Bronx is about 35% higher than the U.S. rate overall,[8] Each year, 30 women in the Bronx die of cervical cancer, a completely preventable disease through screening.[7] Low-income populations are significantly more likely to be diagnosed with preventable and late-stage cancers than the general population, a disparity that may be partially explained by lower rates of cancer screening and delayed follow-ups of abnormal results.[9-12,13-17] Low-income women of all ethnicities, but particularly among racial and ethnic minorities, have lower rates of cervical, breast, and colon cancer screening in the U.S,[18-23,24-26] and in New York City.[27] In fact, socioeconomic status has consistently been found to be one of the greatest predictors of screening [25,17,26] and stage of cancer detection.[17,28,29] Absence of screening is not only a primary predictor of late-stage cancer diagnosis and accompanying morbidity, but also of significantly lower survival rates for breast, cervical, and colon cancer.[25,30,31] Thus, despite improvements in cancer screening rates in the past 20 years, pervasive disparities persist.[32 24 33]

The reasons for the screening disadvantage associated with low SES as well as race and ethnicity include inadequate insurance coverage and concerns about cost; uncertainty about how to access screening; lack of a physician recommendation; language and literacy barriers, including difficulty communicating with a provider; lack of knowledge about cancer prevention; transportation and time barriers; medical mistrust; embarrassment associated with procedures; fear of cancer, the procedures, and/or deportation; perceived susceptibility to the disease; self-efficacy; fatalism, and perceived social norms.[34,35,36,37,24,38,39,40,41,42] Recent systematic reviews have documented many community and clinic based interventions developed over the past 20 years to address these various barriers to screening in low-income minority populations.[43,44,45,26] However, one potential common comorbidity that may create additional barriers to screening, yet has received comparatively little attention in the intervention literature, is mental illness,including depression.

Cancer Screening among Women with Depression

There is a growing body of research indicating that among women in particular, those who experience untreated mental health problems such as depression are significantly less likely to participate in cancer screening behaviors, especially mammography and Pap testing.[47,48,49,14,50,51,52,53] Research has also shown that among depressed, low-income women, lack of physician recommendation, lack of self-

efficacy, and lack of knowledge about cancer and screening were the greatest predictors of non-adherence to age appropriate screening.[54] Two other qualitative research studies examining barriers and facilitators to cancer screening among women with mental illness highlighted physician recommendation and referrals as a facilitator, and deficiencies in knowledge about cancer and screening as a key barrier.[55,56] One of these studies pointed to gaps in communication between primary care and mental health providers as contributing to suboptimal screening in this population, and suggested a need for an enhanced role of mental health providers in facilitating cancer screening of women with mental illness.[56] The relationship between screening and depression is of particular importance to address in low-income, predominantly minority counties like the Bronx. The Bronx not only has high rates of cancer mortality, but also the highest prevalence of self-reported serious psychological distress in New York City, a measure that has been shown to be closely associated with depression and other mental illness.[3] Major depression, a chronic disease,[57,58] is the most common mental health problem, affecting between 20% and 25% of poor minority women;[59-61] in contrast, the prevalence of major depression among the general female population is 10%.[62] An analysis of WHO World Health Survey data on more than 245,000 people in 60 countries showed that depression had the greatest impact on overall self-rated health, and thus the greatest disease burden, compared with other chronic diseases, including angina, arthritis, asthma, and diabetes.[63] Recent results from a national study in the U.S. found that depression is more chronic, severe, and disabling among African Americans than other populations.[64,65] When Hispanics and African Americans seek consultation for depression, it is most likely to be in primary care settings.[66] However, current primary care depression management practices typically fall below accepted evidence-based standards,[67,57,68] particularly for minority patients,[65] although a number of strategies have been shown to be effective in the primary care settings.[69] Moreover, research has also shown that minority women are less likely than white women to go to specialty mental health care for depression when recommended by their primary care provider and are less likely to take anti-depressant medication when it is prescribed.[70,71,72]

Research suggests that to improve colorectal cancer screening in primary care, there is a need for improved efficiency and quality of services, which will require better system supports; improved, culturally competent communication with patients about screening and screening options to facilitate informed decision-making; and multidisciplinary team care, including health educators and care managers.[103] In this intervention we propose to test, the care manager's role is specifically intended to improve the efficiency of patient provider communication as well as efficiency of communication between providers regarding individual patients' needs, in order to maximize patient knowledge and informed decision making, and to optimize care.[105]

The proposed study grew out two lines of research. The first is a recent NIH-funded community-based participatory research (CBPR) pilot project conducted in the Bronx from 2009 through 2011 (Clinical and Translational Science Award UL1 RR0257); project PI was Dr. Elisa Weiss, the co-principal investigator on this grant. The second, described below, is a set of three related NCI-funded studies demonstrating the effectiveness of cancer prevention care management conducted by Dr. Jonathan N. Tobin and team members at Clinical Directors Network and Dartmouth Medical School in Community Health Centers and Medicaid Managed Care Organizations in Manhattan and the Bronx NY.[76,77,78]

The proposed study will test the effectiveness of a novel, combined care management screening and depression intervention within Bronx community health centers, designed to improve uptake of mental health and cancer screening services, enhance quality of life, and increase satisfaction with care decisions. The year-long intervention will provide low-income, depressed minority women 50-64 years of age with the education, support, and assistance they need to make informed decisions about their depression treatment and cancer screening and overcome barriers to utilizing needed services. The findings of this study are relevant for a large number of underserved women and the health centers that serve them. All low-income minority women 50-64 years of age must make breast, cervical, and colon cancer screening decisions, and it is likely that close to one in four of these women will experience depression. In the Bronx alone this constitutes approximately 20,000 women. To our knowledge, despite the Institute of Medicine's (IOM's) identification of both cancer screening and depression as priority areas for action,[73] there have been no studies that have specifically attempted to address major depression as a barrier to cancer screening for low income, minority women.

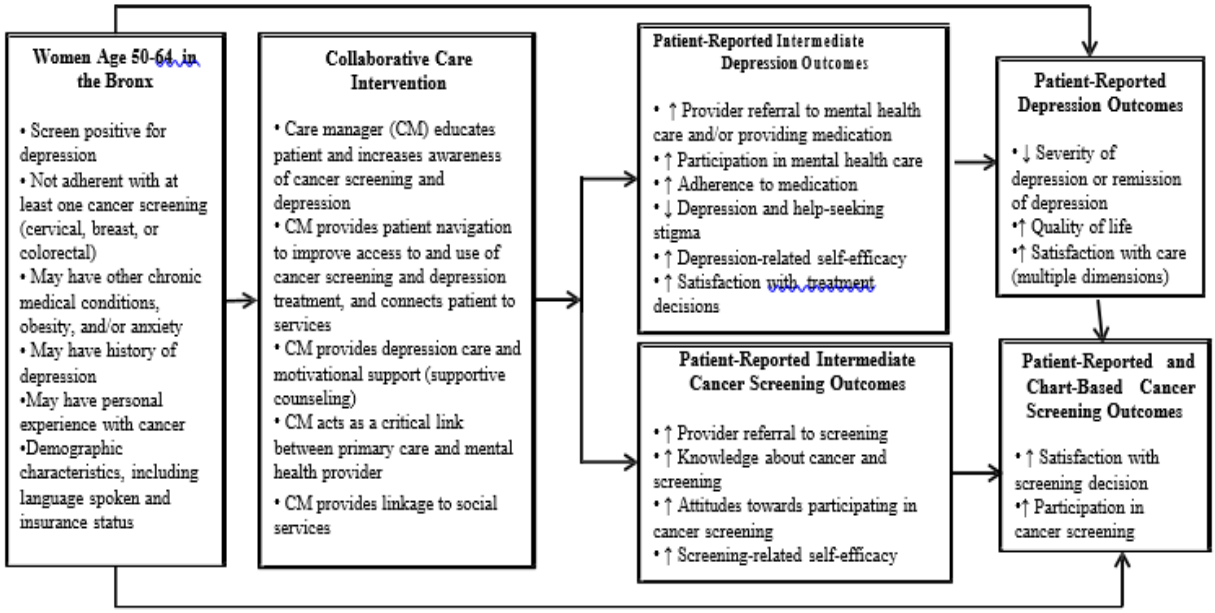
B. OVERVIEW AND STUDY DESIGN

Working with health centers, community-based organizations, and patient stakeholders, this study will seek to determine whether a collaborative care intervention that addresses depression and cancer

screening needs simultaneously among women ages 50-64 in the Bronx is more effective at improving cancer screening and patient-reported outcomes for women with depression than an existing evidence-based cancer screening intervention alone.To achieve this, we will compare the effectiveness of these two interventions using a randomized controlled trial.

The conceptual model guiding this comparative effectiveness study and the elements to be measured to determine effectiveness of the new intervention (see Figure 1) are guided by the theoretical frameworks (PRECEDE-PROCEED and Diffusion of Innovation) described previously, and the related mechanisms of change and expected outcomes that underpin both the PCM (screening facilitation) and TCM (depression reduction) intervention components. Additionally, although the concepts of self-efficacy or stigma are not typically measured in PCM or TCM, these are key barriers to service utilization among depressed, minority women.[47,54,72,99,106] Furthermore, because satisfaction with health care decisions (as distinct from satisfaction with care and one's provider)[107] captures a patient's confidence in her decision and predicts future decisions (e.g., screening, medication adherence)[107,108] we have incorporated this concept into our new, integrated care management intervention model – Collaborative Care Intervention (CCI; see Figure 1).

Figure 1. CCI Intervention Pathways



Approach to Increasing Screening

For the screening-focused components of the intervention, we will use as a foundation the collaborative work of Drs. Allen Dietrich, Jonathan N. Tobin, and colleagues, specifically the Prevention Care Management (PCM) program,[87,77,78] mentioned above as a foundation for the proposed research. Dr. Tobin is PI of this proposed study and Dr. Dietrich will act as a consultant in each year of the project. Ms. Cassells, who oversaw the implementation of the studies to test the effectiveness of PCM is the Project Director of this proposed study. PCM is a telephone-based cancer screening support and system navigation program provided by a trained prevention care manager that has been shown to be effective in increasing rates of breast, cervical, and colon cancer screening across a number of trials and in different kinds of primary care settings, including Bronx community health centers.[87,77,78] PCM is based on the PRECEDE-PROCEED planning framework for health behavior interventions,[37] which posits that success in achieving change is enhanced by the active participation of the intended audience in defining their own barriers and goals and in identifying and implementing solutions.[88,89,90] The implementation of PCM is also guided by Diffusion of Innovation theory,[91] and it recognizes and responds to the different stages that individuals go through in adopting an innovation, here cancer screening. Consistent with Diffusion of Innovation theory, PCM views both knowledge and attitude change as influencing the decision to engage in screening, aims to improve self-efficacy to obtain physician recommendation and referral, and encourages a trial of the innovation. Findings across three NCI-funded PCM studies demonstrate a significant benefit of the PCM intervention in increasing screening rates across primary care practices and managed care organizations, providing strong evidence for its effectiveness, dissemination, implementation reach and sustainability.[9] A Prevention Care Management Staff Training Manual was

developed and adopted by NCI as one of its Research-tested Intervention Programs (RTIPs) in efforts to encourage national adoption of this effective program.[5]

Nonetheless, PCM was not specifically designed to address barriers to screening among depressed patients. The limited yet consistent research on screening among women with mental illness and our pilot study results suggest that a care management intervention aiming to improve screening among depressed women in the Bronx should also encourage active collaboration of mental health providers in cancer screening promotion; address stigma associated with screening and mental illness; and provide linkages to social services to address immediate crises getting in the way of screening and contributing to depression, such as domestic violence. These elements will be included in our new intervention.

Approach to Reducing Depression

To reduce depression in Community Health Center patients who are in need of one or more cancer screening tests, we will draw on an extensively used evidence-based mental health care management model called collaborative care, which grew out of the Chronic Care Model (CCM).[92,68,93] Collaborative care is a multi-component team-based intervention that uses a care manager with or without clinical training (e.g., nurse, social workers, or office medical assistant) to link primary care providers, patients, and mental health specialists; in addition, primary care providers receive consultation and decision support from mental health specialists (psychiatrists and/or psychologists). The collaboration is designed to: 1) improve routine screening for and diagnosis of depressive disorders; 2) increase provider use of evidence based protocols for the proactive management of diagnosed depressive disorders; and 3) improve support for active patient engagement in treatment goal-setting and self-management.[68,66]

For the integrated intervention, or "intervention package"[86] that combines screening and depression care management, we will adapt the evidence-based Three Component Model (TCM) of collaborative care,[97,98,57] and we will incorporate additional evidence-based socio-cultural collaborative care elements developed by Ell and colleagues.[95,99] TCM, funded as part of the MacArthur Foundation Initiative on Depression and Primary care, provides a system for depression management as recommended by the U.S. Preventive Services Task Force, and its structure is complementary to that of PCM. Components include telephone care management, collaboration between mental health and primary care professionals, and preparation of primary care clinicians and practices to provide systematic depression management through training. Based on Ell's successful collaborative care trials with low-income Hispanic populations,[95,99] we will draw on her work to add the following elements to TCM: 1) psychoeducation to dispel treatment misconceptions, reduce stigma associated with depression, and enhance the therapeutic alliance; and 2) patient navigation assistance specifically to facilitate patient self-efficacy, patient-provider communication, access to financial and social resources, with a focus on specific behavioral activities to complete screening examinations and follow-up (e.g., scheduling appointments, reminders, transportation).

Outcomes include: reduced depression, improved quality of life, improved satisfaction with healthcare decisions, increased self-efficacy, decreased internalized stigma, and decreased likelihood of morbidity and mortality from breast, cervical, and colorectal cancer.

Main Hypotheses

Our hypothesis that the 12-month CCI intervention we will implement at the six participating sites will be significantly more effective than the PCM comparison condition in improving key patient-reported outcomes associated with cancer screening and depression, including cancer screening knowledge and attitudes, self-efficacy, depression- related stigma, provider referrals, participation in mental health care, medication adherence, quality of life, and satisfaction with care and treatment decisions, and depression (**Aim 1**).

We expect the intervention to have a positive impact on screening participation itself (**Aim 2**) by reducing depression (**Aim 3**) and by influencing patient-reported outcomes associated with screening. Finally, as shown, we hypothesize that the effectiveness of CCI in comparison to the PCM condition in increasing screening may vary depending on patient characteristics, such as duration of depression, presence of other chronic conditions, obesity, personal experience with cancer, and demographic characteristics (**Aim 4**); we also hypothesize that depression outcomes will vary according to these patient characteristics as well. We recognize that change has both intended and unintended consequences and is not linear. However, our model depicts the hypothesized pathways for the study and analysis as described; any additional analyses of bi-directionality will be exploratory.

To determine the effectiveness of the CCI intervention in increasing cancer screening over a one-year period, we will compare it to the performance of the traditional PCM cancer screening intervention among depressed women who are non-adherent with one or more screenings. Because PCM has demonstrated effectiveness among health center patients of the Bronx in general, such a comparison will be an ideal test of whether addressing and reducing depression are necessary steps to increase rates of screening among low-income depressed women. Utilizing a "usual or standard care" group as the comparison condition instead of the PCM intervention would make it impossible to isolate the effect of adding the depression reduction collaborative care components to PCM. Moreover, because PCM has already been demonstrated to be effective our MHC Connection partnership felt that offering PCM as the comparison condition would be the most ethical approach. If we find that PCM alone works just as well among depressed women as our new, integrated CCI intervention – i.e., if our findings do not enable us to reject the null hypothesis – this too has important implications for the delivery of patient-centered screening interventions in the Bronx and in other areas with a high density of low-income minority populations.

Intervention Content

The PCM intervention components, to be delivered to women randomized to the comparison arm, are a subset of the CCI intervention components, since the new CCIintervention is a combination of PCM cancer screening care management and TCM depression care management. In Figure 2 below, we outline the components of the interventions to be delivered by the care managers in the two study arms, based on the three previous randomized controlled trials of PCM in CHCs conducted by the CDN Team[76,77,109] and on collaborative care. [97,99,110,111] A 12-month intervention period was chosen based on the depression collaborative care literature.[42,96,99,112] PCM was shown to have an effect on cancer screening in eight months.[77]

Figure 2. Intervention Content

	Prevention Care Manager (PCM)	Collaborative Care Model (CCI)
Cancer Screening	• Educate and increase awareness • Provide patient navigation • Provide motivational support to overcome barriers to cancer screening	• Educate and increase awareness • Provide patient navigation • Provide motivational support to overcome barriers to cancer screening
Mental Health		• Provide depression care and motivational support (supportive counseling) • Be an interface between primary care and mental health providers • Provide linkage to social services

Care Managers and Intervention Delivery

The care managers, performing the functions presented in Table 1, will be female bi-lingual college graduates with a social work or health education background, by education or job experience. A number of studies have found that professionals who are not clinically licensed can serve as effective depression care managers, and this reduces the cost and increases feasibility of dissemination and sustainability,[97,110] and more resembles the CHC workforce. There will be two half-time care managers in each CHC, one for the CCI. Based on our discussions with our study sites, we expect that most if not all

care managers will be existing staff who are familiar with the health center culture, providers, and systems, including the electronic medical record and referral sources. For both study arms, the intervention is designed to be deliverable by phone, for efficiency in time and cost;[113-115] however, we anticipate that enrolled patients may want to meet with the care manager in person as well, especially when at the health center for an appointment.

C. STUDY PROCEDURES

Female patients ages 50-64 years of age and identified as out-of-adherence with at least one cancer screening based on the CHCs' electronic medical records will be recruited by care managers in the waiting room or by telephone following a mailed letter. Care managers will receive verbal consent to administer a brief screening tool to assess eligibility for the study, as outlined above; these data will be anonymized, so that it will not be possible to link the screening data back to the individual patient. All women screened will receive $5 for their time. Patients who are not eligible for the study but whose score on the PHQ-9 is indicative of depression ($\geq$ 8) will be asked if they would like help making an appointment at the CHC.

All women who agree to participate in this study will complete a process of informed consent, during which the care manager will discuss the study and its potential risks and benefits, and answer any questions that potential participants might have. It will be made clear that each woman's decision regarding participation in the study will in no way impact her individual access to free or low cost medical care at that particular health center where consent is taking place, or at any other health center. The consent form, like the survey instruments, will be available to participants in English or in Spanish.

Eligible women will be invited to participate in the study. When recruitment is conducted in person, the care manager will make every effort to complete the consent process at that time, and she will also attempt to complete the 45-minute baseline structured interview, described below. If this is not possible, the care manager will schedule another appointment, as soon as possible, to conduct the baseline interview by phone or in person at the CHC. Based on prior collaborative care research with minority patients in these Bronx CHCs and other similar settings, we expect a consent rate of about 70%.[76,99] In keeping with PCM and other collaborative care research,[76,112] we will use a randomized block algorithm, stratified by CHC to assign women to the PCM control arm or the CCI intervention arm. Block size will be allowed to vary randomly to preclude any exercise of judgement, or bias, in the allocation of participants to specific arms. Study participants will be randomized 1:1 to each of the two arms, according to a scheme prepared by the study statistician, who is not onsite at any of the CHCs. Randomization will occur after the baseline interview; women in the study will be notified of their assignment at the time of the first call with the care manager. Mr. Lin, study data coordinator, will disclose the block randomization process and will inform care mangers of the assignments. Ms. Cassells, Project Director, will supervise Mr. Lin and all aspects of data collection described below.

Initial phone contact

At the time of consent, all study patients will receive low-health literacy educational booklets about depression (provided by the NYC Department of Health and Mental Hygiene) and cancer prevention (provided by the NYC Department of Health and Mental Hygiene), in either English or Spanish, depending on their language preference. On the first call with patients, care managers will inform patients of their group assignment; in the PCM comparison arm, care managers will discuss only the cancer prevention information. If a patient asks questions related to depression, she will be encouraged to make an appointment with her primary care clinician. In the CCI intervention arm, care managers will review information provided about both cancer screening and depression. Additionally, in both groups and on the first call, care managers will assess the patient's stage in intending to engage in cancer screening, for each of the types of screening for which she is not in adherence with guidelines. Care managers will use a structured approach to assess the patient's stage of readiness, and she will use this monthly throughout the intervention period in both arms. Specifically, and guided by the Transtheoretical Model,[116] study participants will select one of six descriptions that best matches their past screening behavior and future intentions, from Unaware (never thought about [colon, breast, cervical] screening for myself before now) to Maintenance (routinely undergo screening and plan to continue doing so in the future). Such an assessment approach has been used extensively and validated in ethnically diverse groups with respect to screening intention.[117-120] Finally, the initial phone calls with women in both study arms will include a barriers assessment, which, informed by the Precede-Proceed Framework, involves working with patients to collaboratively identify and problem-solve barriers to screening

participation.[37,87] Women in the CCI intervention arm will also engage in a barriers assessment relating to participation in mental health care utilization and/or medication adherence, as well as participation in social services and self-care. This assessment will be based on the collaborative care work of Ell.[95] The barriers assessments will guide the care managers in working with the patients effectively to achieve self-identified goals screening and mental health goals, which may evolve over the course of the intervention period.

Subsequent phone contact and activities

Following the first phone discussion, care managers assigned to the CCI intervention condition will reach out to patients at least every three to four weeks.[99,121] During these monthly conversations, the care managers will conduct symptom monitoring with the PHQ-9, which works well by phone.[95] They will also provide the elements of depression care management and motivational support as shown in Table 1 above to facilitate treatment decision-making and adherence, and to reduce depression. The care managers will not introduce the topic of screening and screening barriers until barriers to utilization of mental health care and/or adherence have been addressed. However, patients will be aware that the intervention is designed both to reduce depression and increase screening, and if a patient raises screening before the care manager does, this will open the dialogue. Between calls, the care manager will perform the navigation and linkage functions presented in Table 1. Care managers assigned to the PCM control condition will reach out to patients by phone once per month and more as necessary to assist women in overcoming barriers, including negative screening attitudes and transportation barriers, arrange appointments, answer questions, provide needed information, etc., for one year, or until the patient is up-to-date for all screenings.[87,123] The standard, structured PCM phone scripts developed previously will be used to review and problem-solve screening barriers in both study arms,[76] and care managers will facilitate decision-making about the right colorectal screening test for the patient.

Emergency Protocol

Based on the PI's present study of PTSD among Bronx CHC patients, we have developed an emergency protocol for the care managers to follow if, in the course of administering the PHQ-9, the patient endorses thoughts of suicide, or if the patient expresses suicidal thoughts outside the PHQ-9 administration. Prior experience in these settings and other research suggests that we can expect about 10% of the patients to express suicidal ideation.[121]

Care Manager Training

The care managers will be assigned to the CCIintervention group or the PCM comparison condition prior to training. The care managers assigned to the comparison condition will not be trained on depression care management (the second part of the training) during the active study, to further avoid the possibility of contamination across the groups. They will, however, receive training about what to do when a woman is in acute distress and/or is suicidal. The first part of the training, which will be attended by all care managers, will last eight to ten hours over two days. Care managers will be expected to review all study materials prior to the training. PCM Training will be based on the NIH RTIPS for the Dartmouth-CDN Prevention Care Management Project[124] and will be conducted by Ms. Andrea Cassells, the study Project Director, who has conducted PCM training across multiple studies of care management in cancer screening and PTSD in the past 10 years, with support from the study clinical psychologist. Dr. Allen Dietrich, PI for the previous PCM RCTs and the developer of both the PCM and CCI Interventions is a member of the research team and provides training and oversight to the Care Managers. Guided by PCM,[76] care managers will receive an overview of current screening guidelines of the U.S. Preventive Services Task Force; a review of barriers to breast, cervical, and colorectal cancer screenings; and detailed explanations of the screenings themselves. They will role play in the training about how to elicit barriers from women and how to provide motivational support to help women overcome them. Standard scripts will be provided to support the care managers and facilitate uniformity delivery, and they will need to pass a competency test.

The second part of the manual-based training, which will last ten hours over two days, will be didactic and interactive; it will be led by the project psychologist, with support from Ms. Cassells. Only care managers assigned to the CCI intervention will participate in this training; as with the first training, they will be expected to review materials beforehand. The focus will be on depression care management and will entail a review of what depression is, including key symptoms, as well as a brief overview of anxiety, which is likely to present in approximately 50% of the depressed women.[121] Guided by the work of Ell and colleagues[95,99] care managers will also learn about barriers to help-seeking for mental health

problems, depression medications and barriers to adherence, and stigma and related cultural beliefs. Additionally, the mental health services offered in each care site will be reviewed, and there will be a discussion about how to best communicate with the primary care clinician regarding a patient's mental health needs, and how to fulfill the essential linkage role between the primary care clinician and a mental health specialist.[57,111] Also, in order for the care manager to be effective in her role, she must learn how to monitor treatment-response and depression through patient self-report.[57,105] For this monitoring, and to guide changes in treatment, we will use the PHQ-9, which is already widely used in many CHCs, and in studies of collaborative care,[57] and is described in the measures section.

Care Manager Supervision

Dr. Allen Dietrich, PI for the previous PCM RCTs and the developer of both the PCM and CCI Interventions is a member of the research team and provides training and oversight to the Care Managers. The care managers assigned to theCCI intervention arm and the PCM intervention arm will have monthly case management meetings, in order to facilitate group problem-solving, skill-building and to provide a forum for mutual support.. [57,67]

Care Management Monitoring and Process Evaluation

To help ensure that both arms of the intervention are implemented as planned (i.e., to assess treatment fidelity), care managers will use an electronic database to document all contacts with patient, including date, time, duration and mode (by phone or in-person), and content of the discussion. Care managers will also document specific barriers or problems mentioned and how these were addressed, stage of screening readiness at monthly intervals, and issues that arise in the CHC that either facilitate or hinder their work. The investigators on the research team will systematically review these process data weekly during the first month of implementation, and then again monthly in the first year. An implementation science framework that recognizes the challenges in translating evidence-based practices to CHCs[86,111] will guide our approach to the process evaluation. These data will be brought for discussion to the Stakeholder Advisory Group meetings, as described in the Stakeholder Engagement Plan.

Education of CHC Clinicians and Staff

Primary care capacity-building is a key aspect of TCM, and we will incorporate some of this here. Specifically, in keeping with TCM, primary care clinicians at each CHC will be told about the study and will receive a two-hour CME-accredited onsite educational program/refresher that addresses the diagnosis of depression, assessment of suicidal thoughts, use of the PHQ-9 as an aid to diagnosis and treatment monitoring, the role of care management, and the use of decision support to modify management and achieve remission of depression.[121]

Office staff will receive a one-hour in-service session about the study, an overview of depression diagnoses and management, and procedures to facilitate communication between providers and the care manager.[121] We do not believe that this education will contaminate the comparison condition, because literature repeatedly shows that basic training alone to providers about depression does bring about practice chance in and of itself.[57] A key part of collaborative care is to encourage and support clinicians to identify and treat depression, with mental health consultation and as they feel comfortable, and the site investigators/PIs (described in People and Places) will play a key role in facilitating this. At all health center sites sites, there is mental health consultation and patients will have access to short-term therapy as well as cancer screening services or referral to nearby services with only short wait times.

Procedures for Data Collection to Evaluate the Comparative Effectiveness of the Two Interventions

To compare the effectiveness of the two interventions, we will collect structured interview data from study participants, including data at baseline and then again six and 12 months later. Data will be collected by phone or in person as needed by bi-lingual recruitment coordinators, who will be blinded to the participants' study assignments. To maintain this, before beginning each interview, the Recruitment Coordinators will ask participants not to refer to their care manager by name, but rather as "my care manager." All measures described below as patient self-report (rather than chart review) will appear in each of the three interviews, with the exception of basic demographic items. We expect that the interviews will take about 45 minutes to complete. Patients will receive $10 for participating in the first and second interviews and $15 for the third interview.

D. STUDY DRUGS

N/A

E. MEDICAL DEVICES

N/A

F. STUDY QUESTIONNAIRES AND MEASUREMENT

We chose measures that are based on the conceptual model, have been validated and used widely with minority populations, and have been translated into Spanish; as needed, we will use a translating service with forward and back translation to translate the measures. All items taken from the National Cancer Institute's HINTS survey have been translated. We organize the measures by: primary outcomes, intermediate outcomes, and co-variates.

Primary Outcomes

Participation in colorectal, breast, and cervical cancer screening

We will assess participation in age-appropriate cancer screening behaviors in two ways:

a.Chart Review: Review of electronic medical records at each of the three CHCs.

b.Self-Report: We will ask participants about their participation (yes/no) in specific screening methods: Pap testing (past 3 years), mammography (past 2 years), and colorectal screening (FOBT/FIT, past year; flexible sigmoidocopy, the past 5 years; and colonoscopy, past 10 years). We will use standardized items from the NCI's HINTS Survey.[127]

Depression

a. Patient Health Questionnaire (PHQ)-9. The PHQ-9 is the 9-item depression module from the full PHQ, and is a well-validated Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV) criterion-based measure for screening and diagnosing depressive episode, assessing severity, and monitoring treatment response,[128,129,130,131] either in person or over the phone.[132] It has been shown to measure a common concept of depression across racial and ethnic groups, including African Americans and Latinos.[128 133] Cronbach's alpha was 0.80 in both African American and Latino samples.[128] As a severity measure, the score can range from 0-27, since each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day). Meta-analysis showed pooled sensitivity of 0.80 and specificity of 0.92 to a diagnosis of major depression among primary care patients in a structured psychiatric interview by a mental health professional using DSM-IV diagnostic criteria.[131] As a practical screening tool, patients with a score of > 10 are considered to have clinically significant depressive symptoms.[99,134,96,112,135,129]

b. The Hopkins Symptom Checklist (SCL-20). The SCL-20 consists of the 20 depression items on a 4-point scale from the SCL-90, and has been shown to be a valid and reliable measure of depression in diverse outpatient and community populations (Cronbach's alpha = 0.87; test-retest r=0.81).[136,137] It has been shown to be sensitive to change in studies of collaborative care in primary care settings[99,97,121,96,112,134,135] and among minority group patients.[95,99,133]

We will consider clinically meaningful improvement of depressive symptoms to be a > 50% reduction in baseline SCL-20 or PHQ-9, and depression remission as an SCL-20 score <0.5 or a PHQ-9<5.

Intermediate Outcomes

Quality of Life/Health Status. We will measure quality of life with the Medical Outcomes Study (MOS) Short Form Health Survey (SF-12), which includes heterogeneous items from the SF-36 physical and mental component scales. This general measure of health status assesses the patient's perceived health status and whether health problems interfere with normal functioning. The SF-12 has with demonstrated validity and test-retest reliability in the general population and in patients with chronic health conditions, and has been tested in five languages, including Spanish.[138] It has been used extensively as a quality of life measure in collaborative care studies,[42] including with low-income minority populations.[95,99] It has also been used frequently in screening studies, for cancer and other conditions.[139-142] The SF-12 has been validated as an indicator of effects of depression on quality of life in ethnically diverse patients.[143]

Mental Health Care Utilization.

We will assess mental health care utilization in two ways:

c. Chart review. We will use data from the electronic medical record to determine the number of health visits, and the kind of provider seen for mental health care (psychiatrist, psychologist, and/or clinical social worker).

d. Patient report. At baseline, we will ask respondents how many times in the past six months they have seen a provider to talk about or get medication for feeling sad, nervous, hopeless, or blue. In addition, we will ask participants about their ability to arrange to get mental health treatment, as well as whether they

have the financial resources to access mental health services. These questions will be adapted from the NCI's HINTS survey.[127]

Satisfaction with decision to participate in screening and mental health care. The Satisfaction with Decision Scale is a 6-item measure that uses a five-point Likert-type scale and can be tailored to any healthcare decision; it is grounded in a conceptual model of an effective decision, i.e., one that is informed, consistent with the decision-maker's values, and behaviorally implemented.[107] It has excellent validity and reliability (Chronbach's alpha=0.86) in samples of women 40 and older,[107] among depressed patients,[108] and among participants of a large national cancer screening trial.[140]

Attitude Toward Cancer Screening

We will use questions from the NCI's HINTS survey[127] to assess patients' attitudes and beliefs about colon cancer screening that might prevent them from obtaining this cancer screening. We will adapt this item to also assess patients' attitudes and beliefs about cervical cancer and breast cancer screening.

Stigma associated with depression and help-seeking. *Internalized stigma*, also referred to as self or felt stigma,[158] will be measured with Link's Devaluation-Discrimination Scale (DDS) (Link, 1987; Link et al., 1989 and 1991). This 12- item extensively used measure, based on modified labeling theory, uses a six-point Likert format and assesses the extent to which an individual believes that people with mental illness are devalued or discriminated against (Link et al., 2004). It has established validity and reliability in diverse and low-income urban patients.[159,160] The average Cronbach's alpha for this scale was .83.[158] We will also measure *stigma-related concerns about seeking care*, based a large study of lowincome Black and Latina women with depression.[72] A care-seeking stigma variable will be created from 3 yes/no in response to the query: Would any of the following keep you from getting professional help? Participants will be categorized as having stigma -related concerns if they endorse one or more of the following: being embarrassed to talk about personal matters with others, being afraid of what others might think and family members might not approve.

Satisfaction with care. In keeping with the Institute of Medicine's report Crossing the Quality Chasm (2001) and with recommendations based on a systematic literature review (Crow et al., 2002), we will use a 34-item multidimensional scale of patient satisfaction that has demonstrated high reliability and construct validity in large outpatient samples, including Medicaid patients and Spanish-speaking patients (Safran et al., 2005; Fanjiang et al., 2007). The Ambulatory Care Experiences Survey produces 11 summary measures covering 2 broad dimensions of patients' experiences: quality of physician-patient interactions and organizational features of care. All measures range from 0 to 100 points, with higher scores indicating more favorable performance. Cronbach's alphas for the 11 measures range from .70 to .90.

Self-Efficacy. We will use the 10-item General Self-Efficacy Scale (GSE).[161] The scale measures a general sense of perceived self-efficacy associated with coping with daily hassles and adapting to stressful life events. This unidimensional scale is available in 33 languages and has Cronbach's alphas ranging from .76 to .91 based on samples from 23 countries.[162] Perceived self-efficacy is an operative construct, meaning that it is related to subsequent behavior and is relevant for clinical practice and bringing about behavior change.[161] However, it does not tap specific behavior change, and thus it will be necessary to add items to focus on the three different types of screening and utilization of needed mental health services; the development of such items will be based on the guidelines of Schwarzer[161] as well as the valid and reliable breast cancer screening self-efficacy measurement work of Champion[163,164]; the cervical cancer screening self-efficacy work of Fernandez; [157,165] and research by Maly[166] on efficacy in patient-physician interactions.

Physician recommendation of screening/mental health care. We will use questions from the NCI's HINTS survey[127] to assess whether patients report their primary care physician has recommended cervical, breast, and colon cancer screening. We will adapt this item to determine whether their primary care physician has recommended that the patient make an appointment with a mental health provider and/or take psychotropic medication.

Mental health treatment adherence. We will ask respondents if they have been prescribed medication for depression and about difficulties taking medication(s) regularly. Questions will adapted from Katon's Team Care Intervention.[112]

Co-variates

Sociodemographics. We will draw the following measures from the NCI's HINTS survey;[127] race, ethnicity, age, education, language spoken, foreign born, years in the U.S., marital status, parental status, household composition, employment status, insurance status, education, and income.

Past history of cancer. We will use questions from the NCI's HINTS survey[127] to determine whether the respondent has ever been diagnosed with cancer, and if so, what type of cancer and when. We will also ask women if they have had a hysterectomy and confirm through the electronic medical record whether this was a full hysterectomy that included removal of the cervix.

Family history of cancer. Questions about family history of cancer will come from the NCI's HINTS survey.[127]

Chronic medical conditions and obesity.

Information about the respondents' chronic medical conditions as well as weight, height, and body mass index as an indicator of obesity will be drawn from the electronic medical records. **Anxiety (GAD-7).** The GAD (Generalized Anxiety Disorder)-7 is based on diagnostic criteria in the DSM-IV and measures probably anxiety disorder and severity of anxiety symptoms. Patients are asked to rate how often they have been bothered by 7 problems in the last 2 weeks on a 4-point (0-4) scale ("not at all" to "nearly every day"). At a cut point of 10, sensitivity is 89% and specificity is 82%. In multiple diverse primary care samples of over 2000 patients, the measure demonstrated excellent validity as well as high internal reliability and test-retest reliability (Cronbach's alpha=0.92 and intraclass correlation=0.83, resp.).[167,168] Factoral analysis demonstrated that the GAD-7 measures anxiety as distinct from depression.[168] A Spanish-language version has also demonstrated very good specificity and sensitivity as well as excellent reliability and validity.[169]

G. STUDY SUBJECTS

We will recruit 800 women to the study. To be eligible for the study, women must be patients at one of the six participating Bronx CHCs. They must also be between 50 and 64 years of age, speak English or Spanish, reside in the Bronx, screen positive for depression based on the PHQ-9 ($\geq$ 8) at time of recruitment, and be out-of-adherence with current U.S. Preventive Services Task Force cancer screening guidelines for breast, cervical, and/or colorectal cancer screening. Women will be considered out of adherence if they have not received a Pap test without HPV in the past three years or a Pap test with HPV in the past five years, a mammogram in the past two years, and/or one of the following forms of colorectal screening: FOBT (or FIT) within the past year, flexible sigmoidoscopy in the past five years, or colonoscopy in the past 10 years. A woman who has had total hysterectomy is considered up-to-date for cervical cancer screening after the date on which the hysterectomy was performed.[76] We aim to be as inclusive as possible in this study. However, to maximize feasibility and in keeping with prior collaborative care research[99,112], we will exclude women who report the following when screened: terminal illness, current pregnancy (albeit unlikely in this age range), substance use, decisionally impaired or suicidal thoughts. We will exclude prisoners. Data received from the six health center sites support the availability of potential study participants and demonstrate the need for a study such as this one. In 2011, across the study sites, mammography rates for women 50-64 years of age were 56%, 57% and 64%; Pap testing rates were 62%, 50% and 53%. All of these rates fell substantially below the New York City target of 85% or greater. For colon cancer screening, rates in 2011 were 24%, 52%, and 27%, also much lower than the New York City target of 60% or greater. Additionally, depression rates for women of this age range in 2011 were 35% (including dysthymia), 21%, and 21%, which is consistent with the literature.

H. RECRUITMENT OF SUBJECTS

Participating sites are Morris Heights Health Center, Urban Health Plan and Montefiore Primary Care Practice. We have added Segundo Ruiz Belvis and Morrisania Diagnostic and Treatment Centers and Lincoln Primary Care Practice as three additional sites. We will recruit approximately 800 women ages 50-64 who screen positive for depression and who are non-adherent with cervical, breast, and/or colorectal cancer screening guidelines from one of the participating Bronx sites. Women in this age range should receive all three types of cancer screening. We are focusing solely on women because estimates of depression among minority women in the Bronx are 20%-25%, at least twice that of men, and depression has been shown to be a barrier to screening, with consequences for cancer morbidity and mortality. Patients will be approached and screened in the participating sites in person or by phone to

determine whether they meet initial study inclusion criteria; they will have been identified as potentially eligible by the electronic medical record. Only patients who speak English or Spanish are eligible. For this screening, patients will provide verbal consent; the data will be anonymized. Patients will receive $5 for their participation in the screening. If a patient confirms through this initial screening that she is out-of-adherence for one or more types of cancer screening (breast, cervical, and/or colorectal), the patient will be administered the Patient Health Questionnaire (PHQ)-9 to determine whether she meets criteria for depression. Those patients who score greater than or equal to 8 on the PHQ-9, do not have a terminal illness, are not pregnant, are not prisoners, are not decisionally impaired and are not active substance users will be asked to provide written informed consent to participate in the study. Patients will be told that study involvement entails speaking with a care manager at least once per month by phone or in-person, as they prefer, and they will be told about the two arms of the study and the randomization process. They will also be informed that participation will involve completing a baseline interview at the time of screening or within the week, as well as two follow-up interviews at 6 and 12-months after the baseline assessment.

The interviews can also take place by phone. Interview content will include basic demographics, questions about barriers to and use of medical and mental health services, physical and mental functioning including depression and anxiety symptoms, self-efficacy, stigma, attitudes towards cancer screening, satisfaction with care and decision-making, and health history information. Interviews will last approximately 45 minutes, and respondents will be compensated for their time: $5 for the prescreening; $10 for the first assessment; $10 for the 6-month assessment; and $15 for the 12-month assessment. This study is open to accrual of women only, because women are significantly more likely to suffer from depression, which has been shown to be related to cancer screening. We are also limiting our sample to women ages 50-64, since only women within this age range need all three types of preventive cancer screening: breast, cervical, and colorectal. Based on the demographics of patients treated at the health centers in our study, we expect that our female study sample will closely mirror the population of the Bronx. Subjects will not be excluded from participating in this study on the basis of race, ethnicity, socioeconomic status, or insurance status. Every attempt will be made to enter all eligible subjects into this protocol and therefore address the study objectives in a population representative of depressed females 50-64 years of age in the Bronx.

Finally, our analysis plan includes strategies to examine whether study outcomes differ by patients' demographic characteristics, including race, ethnicity, and language spoken. Patient recruitment and follow up need to be optimized in a randomized controlled trial. In order to maximize our likelihood of reaching our recruitment and follow-up goals, we have recruited and engaged three Community Health Centers and three NYC Health + Hospitals Corporation (HHC) practices that that have worked with CDN and Einstein previously on NIH-funded research studies, and have the infrastructure and senior clinical leadership support for initiatives of this kind. Morris Height Health Center, Urban Health Plan, Montefiore CFCC, Segundo Ruiz Belvis D&TC, Morrisania D&TC and Lincoln Ambulatory Practice have all collaborated with CDN on previous NIH-funded randomized controlled trials with interventions and evaluations that include many of the same elements that are proposed in this study, and these practices have been successful at meeting their recruitment goals, and have achieved retention rates of 80% or greater.

For recruitment of patients, we will use a dual approach, clinician referral and identification of prospective participants by encounter data, which has been proven to be successful in previous CDN practice based research initiatives. In order to maximize the number of patients that complete the 6-month and 12-month study visits, we will use a standardized system to track participants through the study. We will obtain extensive locator information subsequent to informed consent, including addresses/phone and cell numbers of participants' family and friends as well caseworkers and social service agencies with which they are involved. Locator information will be updated at each study visit. An EXCEL database will be maintained to track projected study visit dates of each participant. Tangible incentives, including incentives in escalating amounts were built in for compensation of all study visits.

The proposed study will be open to women of all ethnic and racial backgrounds between the ages of 50 and 64 years who speak either English or Spanish. Based on data obtained from our previous cancer prevention projects in Bronx sites;we expect that this female sample will be half African-American and half Latino, roughly reflecting the racial and ethnic profile of the Bronx. We also expect that about half the sample will speak Spanish as their primary language.

I. CONFIDENTIALITY OF STUDY DATA

Confidentiality of each participant's self-report information from the interviews as well as information extracted from the medical records will be secured to ensure patient confidentiality. Study data that will record participant names include informed consents and contact forms. This information will be maintained by CDN staff and stored in a locked cabinet and separate from all other study data. All data sheets will be coded with an ID number to protect confidentiality and will be kept in locked filing cabinets that will be accessible only to the research staff. A master list with matching participant names and code numbers will be maintained in a password protected file on CDN's Local Area Network.on separate sheets of paper, which will be kept in locked storage accessible only to the CDN staff. Any computers that are used to maintain
project data will require passwords for access, and any files containing patient names will also be encrypted and protected by password. Participants will be told that discussions and interview data will be kept confidential. The CDN staff will never link participant responses with identifiable data – that will only be used for the purposes of recruiting participants.

The master list of names will be destroyed at the end of the project . The signed consent form will be kept in a locked file cabinet and then destroyed, along with all remaining project records, seven (7) years after the end of the project

All backup devices containing project data will be kept in a locked cabinet and only project staff authorized by the PI will have access to these data. Scientific presentations and publications will not use identifying information and will preserve the confidentiality of the participating CHCs, clinicians and patients; data will only be reported in aggregate form.

All investigators who have not done so already will complete necessary coursework regarding protection of human subjects and will receive certification from the Collaborative IRB Training Initiative (CITI). The CDN IRB and the IRBs of the three health centers will oversee this study. Also, a Data and Safety Monitoring Plan (DSMP) will be developed and will examine mental health adverse effects (e.g., frequency of severe depression requiring hospitalization, expressions of suicidality), as well as evidence of early superiority of either arm at increasing cancer screening, both requiring early study termination.

The PI/Co-PI and project staff will remain blinded and only the study statistician will have access to unblinded data. Should statistically significant differences arise during the interim analyses, these results will be shared with the IRBs at CDN and the health centers, and a decision to terminate the study will be made at that time. The DSMP developed will be designed to ensure the health and safety of research participants, and it will be designed collaboratively, with involvement of all investigators and the Stakeholder Working Group.

J. POTENTIAL CONFLICT OF INTEREST

None noted.

K. LOCATION OF THE STUDY

The primary institution of the PI, CDN, has seven contractual agreements that bring together community organizations, mental health experts, community health centers, and an academic university with faculty expertise in cross-sector partnerships and biostatistics. The PI, Dr. Tobin, along with his parent institution, CDN, as well as the contractors and their parent institutions are all aware of and agree on the appropriate programmatic and administrative personnel at each organization involved in the PCORI application and are aware of the applicant organization's consortium agreement policy. Should this study be funded, all agencies and individuals are prepared to establish the necessary inter-organizational agreement consistent with that policy.

Practice Sites

The proposed study brings together six practices, including two federally qualified health centers (Urban Health Plan, Inc. and Morris Heights Health Center), two Diagnostic and Treatment Centers that have FQHC look-alike designation (Segundo Ruiz Belvis and Morrisania D&TCs) and two ambulatory care practices (Montefiore Family Care Center and Lincoln Ambulatory Practice) to be the recruitment

sites for this study. These centers bring their years of expertise delivering primary and specialty care to the residents of the Bronx and will act as the medical providers for all participants in this study. Briefly, **Urban Health Plan, (UHP),** is a network of community health centers in the Bronx and Queens, NY (this study will work with all of UHP's Bronx based sites). The mission of UHP is to improve the health status of underserved communities. As a Federally Qualified Health Center (FQHC) and a level III patient centered medical home, UHP offers a broad array of primary and preventative medical services, dental, mental health and specialty services. In 2011, UHP served 48,000 patients through 250,000 patient visits at eight clinic sites, seven school-based clinics, and four off-sites (e.g., homeless shelters, adult day care centers). UHP was one of the first FQHCs in the country to implement an EHR.

As a result, UHP is in a unique position to assist in customizing systems to meet the service–reporting and quality improvement demands of both New York State and the Federal government. In fact, UHP is nationally recognized for its quality improvement initiatives (QI) and has conducted QI initiatives for both cancer screening and mental health. This expertise and experience with QI is a great strength that UHP will bring to this study as both a recruitment and intervention site and as a key stakeholder. Like UHP, **Morris Heights Health Center** (MHHC) is also a non-profit organization, a Federally Qualified Health Center, and a level III patient centered medical home. It has been a leading provider of primary healthcare to Morris Heights and the surrounding areas in the Bronx since 1981, and its mission is to provide high-quality, affordable, and accessible healthcare to all. The Center serves more than 48,000 patients annually, 76% of whom live at, or under, the poverty level providing primary, specialty, dental, mental health, educational and social services. MHHC is unique in the Bronx in that it operates both article 28 and article 31 mental health clinics. As a result, they bring not only expertise providing care to their patients and the community, but also an in depth understanding of the mental health care system in the Bronx. As the largest and oldest ambulatory care teaching site in the Montefiore system, the Montefiore **Family Care Center** (FCC) brings the unique strength and perspective of an academic teaching center. Like UHP and MHHC, FCC serves a primarily low-income population providing both primary and specialty care services. In 2011 the Adult Medical Practice had nearly 45,000 visits serving approximately 15,000 unique patients. CDN, the lead institution, has long-standing collaborative relationships with UHP, MHHC, and Montefiore.

Lincoln Hospital Ambulatory Care Services, Morrisania Diagnostic and Treatment Center and Segundo Ruiz Belvis Diagnostic and Treatment Center are part of NYC Health + Hospitals Corporation and have a longstanding history of providing quality comprehensive medical care to low income and underserved patients in the Bronx.

L. POTENTIAL RISKS

There are no physical risks posed by this study, and the risks of participation are minimal. However, we are targeting patients with depression who may report experiencing distress during an in-person or phone interview with study staff, or during a phone or in-person visit with a care manager. The level of distress participants may experience can range from minimal distress (fleeting and not disruptive to the patient's functioning) to significant distress (patient is unable to refocus and activities are disrupted). Our experience from prior research studies is that such extreme reactions are very rare; however, patients who experience distress at any of the study visits will be referred to their Primary Care Clinician for follow-up care. An Emergency Protocol has been developed detailing the steps and key personnel that need to be contacted in the event of an emergency, such as suicidal thoughts.

M. POTENTIAL BENEFITS

Although we cannot guarantee benefits from participation in this study, all participants will be randomized to one of the intervention conditions and will receive care management services with a focus on cancer screening, or on cancer screening and depression management. All participants will receive information about cancer screening and support to help them make cancer screening decisions. Some participants will also receive information about depression and depression care management.

N. ALTERNATIVE THERAPIES

N/A

O. COMPENSATION TO SUBJECTS

All women screened will receive $5 for their time. Patients will receive $10 for participating in the first and second interviews and $15 for the third interview.

P. COSTS TO SUBJECTS

The cost to each patient for taking part in this project is the time spent with the Care Manager, the time spent taking the screening tests, and the time spent answering the questions during the three (3) interviews. If the patient has health insurance, the screening tests will be covered by the patient's insurance. If the patient does not have health insurance, we will work with the patients and their practices to find ways to pay for the breast, cervical, and colon cancer screening tests they need.

Q. RADIATION OR RADIOACTIVE SUBSTANCES

N/A

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