



Client-Centered Care Coordination (C4™) for HIV/STI Prevention: a Theoretical, Conceptual, and Methodological Overview—HIV Prevention Trials Network (HPTN) 073

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Abstract

Introduction There are few culturally informed, theory-driven evidence-based strategies to support PrEP use among Black MSM. This paper describes the theoretical foundation and conceptual development of C4™ to support the prevention of HIV and other STIs.

Methods C4™ integrates self-determination theory with comprehensive risk counseling and services using an integrative anti-racism lens. C4™ was implemented in a 52-week HIV prevention demonstration project to facilitate PrEP use and adherence among Black MSM ($N=226$) in three US cities from 2014 to 2017.

Results PrEP use was 79%, with 91% of PrEP users starting within 30 days. Twelve-month retention in C4™ was 92%. Care coordination encounters focused primarily on clients' needs related to PrEP adherence (43%) and sexual health (19%). Over the 12-month period, a substantial proportion of the men made progress towards their PrEP adherence goals at the 8-week (83%), 26-week (75%), and 52-week (81%) study visits.

Conclusions C4™ is a multi-level, multi-component intervention that dually targets individual-level motivations and capacities of Black MSM and the healthcare facility-level attitudes, behaviors and processes that characterize the climates where Black MSM receive services.

Policy Implications.

Public health policy efforts to scale-up PrEP may consider C4™ as a tool to optimize the use of PrEP and PrEP program retention with Black MSM. C4™ is also a tool for healthcare facilities to transform their models of service delivery towards improving the implementation PrEP services, including ensuring racial equity in the prevention impact of novel PrEP formulations such as long-acting injectable and potential future long-acting oral regimens.

Keywords Care coordination · Client-centered · Self-determination theory · Pre-exposure prophylaxis · PrEP · HIV/STI prevention · Black MSM

Introduction

Black men who have sex with men (MSM) have been severely affected by HIV-related health inequities in the United States (US) (CDC, 2015; Mayer et al., 2014; Millett et al., 2012; Sullivan et al., 2015). A recent systematic review of HIV incidence among Black MSM ($N=2898$)

predicted that 40% of a Black MSM cohort would acquire HIV by the age of 30, while 61% would acquire HIV by the age of 40 (Matthews et al., 2016). Epidemiologic research has observed that delayed HIV/STI testing, diagnosis, and treatment; suboptimal PrEP uptake and adherence rates; and low HIV virologic suppression contribute to the increased probability of HIV exposure that facilitates HIV/STI acquisition and transmission risk among Black MSM (Choi et al., 2013; Gray et al., 2014; Hall et al., 2013; Hickson et al., 2017; Mannheimer et al., 2014; Millett et al., 2012).

Structural-level vulnerabilities (e.g., income and education disparities, unemployment, inadequate access to

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healthcare, and HIV prevention and care), incarceration, stigma, and discrimination have had a considerable impact on HIV-related health inequities among Black MSM (Ayala et al., 2012; Irvin et al., 2014; Jeffries et al., 2017; Levy et al., 2014; Nelson et al., 2016; Quinn et al., 2019). Levy et al. (2014) reported that suboptimal access to culturally responsive healthcare and prevention services, stigma and discrimination, incarceration, and poverty were indicative of structural factors for HIV testing and prevention services for Black MSM. Recent job loss and economic instability were associated with HIV sexual risk behavior and recent incarceration and housing instability were associated with higher likelihoods of having an STI diagnosis among Black MSM (Nelson et al., 2016). In the same study, another analysis found that, compared to Black MSM without HIV, newly HIV diagnosed Black MSM were younger in age (< 30 years), unemployed, reported frequent insufficient income, had a recent STI diagnosis, and reported condomless receptive anal intercourse with sexual partners within the last six months (Mayer et al., 2014). These stark racial disparities persist despite major advances in HIV prevention science, including the efficacy of PrEP and evidence supporting treatment as prevention through HIV viral load suppression of sexual partners (Fauci et al., 2019).

Emphasis in the HIV prevention field has shifted towards research on the implementation of evidence-based models of prevention to demonstrate public health impact on reducing numbers of new HIV infections (Herbst et al., 2012). Local public health departments and other community-based organizations have an important role in bringing new advances to scale; however, few models have been developed that focus specifically on addressing the structural and psychosocial barriers faced by Black MSM that can undermine their HIV/STI prevention goals (Maulsby et al., 2013). Existing models for Black MSM are primarily behavioral interventions that operate at the group (Herbst et al., 2014; K. T. Jones et al., 2008; Wilton et al., 2009) or individual-level (Arnold et al., 2015; Operario et al., 2010). Other interventions, such as Mpowerment—a community-level behavioral intervention—have been adapted for specific use with Black MSM (Hays et al., 2003; Kegeles et al., 1996). Nonetheless, there remain gaps left by these behavioral interventions that do not address other important targets (healthcare systems barriers and structural impediments embedded within social institutional) and populations (health providers) (Nelson et al., 2014).

Care coordination models had popular use earlier in the HIV epidemic. The United States Health Resources and Services Administration (HRSA) was an early pioneer in the successful use of care coordination models to improve medical care outcomes in patients whose health-related needs were impacted by other comorbid and psychosocial and structural complexities (Gaglioti et al., 2017; C. D.

Jones et al., 2015; Kranz et al., 2018; Pourat et al., 2019). The HRSA Ryan White HIV/AIDS program successfully advanced the use of care coordination to improve medical outcomes among people living with HIV/AIDS (Irvine et al., 2015; Jordan et al., 2013; O'Donnell et al., 2020; Robertson et al., 2019, 2020). Outside of HRSA funded healthcare facilities, including organizations that focused on HIV prevention, care coordination models were largely abandoned in favor of the novel behavioral interventions that were being developed (HIV/AIDS Prevention Research Synthesis Project, 2020), such as Many Men Many Voices/3MV (Wilton et al., 2009), Mpowerment (Kegeles et al., 1996), Healthy Relationships (Kalichman et al., 2001), and Voices/VOCES (Harshbarger et al., 2006). As more scientific evidence on the influence of structural and social determinants on health—including HIV infection—continued to emerge, there was a growing recognition of the resurgent need for prevention models that can accommodate both the clinical and social complexities of life that many Black MSM experience (Nelson et al., 2016). A major limitation to some models of care coordination is the lack of theoretical orientation to guide care coordination activities, which can result in a collection of activities that are not grounded by a sound internally consistent logic and lead to inconsistencies in their implementation (Lamb, 2014; Peterson et al., 2019). Another limitation has been the focus on coordination activities without sufficient attention to theory-based counseling as a key component of supporting a client's motivation to initiate and maintain behaviors that are antecedent to health outcomes (Brown et al., 2014; Cohen, 2011).

Behavioral interventions have typically focused on the attitudes and behaviors of individuals who are targeted for health behavior change. These interventions primarily consider the intra-psychological factors of the individual, while some extend into the meso-level social factors—including social, sexual, and familial networks (Herbst et al., 2007; K. T. Jones et al., 2008; Nelson et al., 2014; Wilton et al., 2009). Many behavioral interventions do not consider the healthcare setting as a social-contextual factor that influences health and healthcare-seeking behaviors of Black MSM (Maulsby et al., 2013). Power dynamics present in the healthcare encounters between clients and healthcare facility staff can be influenced by intersecting homophobic and anti-black racist attitudes towards Black MSM (Arrington-Sanders et al., 2020). Such dynamics can create psychological distancing on the part of the client and staff, which may generate reluctance to follow clinical advice and lead to disengagement from care.

The objectives of this article are to provide theoretical, conceptual, and methodological overviews of the client-centered care coordination (C4™) model of HIV/STI prevention. Client-centered care coordination is an approach to engagement that focuses on supporting the autonomy

of the client, developing authentic closeness, and providing resources (knowledge, material, or referrals/linkages) that facilitate clients to meet their HIV or PrEP health and social needs. It was developed and used to support HIV prevention—including HIV pre-exposure prophylaxis (PrEP) use—among Black MSM. C4™ employs an integrative anti-racism lens and is grounded in both social psychological theory (i.e., self-determination theory) and HIV prevention case management (i.e., comprehensive risk counseling and services). C4™ was developed to address initiation and adherence to antiretroviral medication for PrEP among participants enrolled in HPTN 073 (Wheeler et al., 2019). The C4™ model also considers the healthcare settings (and its component agents) as central components of the motivational milieu of clients and thus a main reciprocal target of intervention.

Theoretical Overview

Integrative Anti-racism

Integrative anti-racism is the overarching analytic lens through which C4™ was conceptualized (see Fig. 1). Integrative anti-racism is a lens through which to view the ways that social oppressions impact the health of marginalized and oppressed groups including, Black MSM. Several theories posit the ways that marginalized social identities intersect to negatively impact on the health of individuals and

communities (Crenshaw, 1993; Graham et al., 2011). Intersectionality is a widely known theory in social science and its use is rapidly growing in public health intervention research. Intersectionality contends that the experiences of marginalized people exist at the nexus of multiple forms of oppression. Integrative anti-racism accepts the premise of multiple interlocking forms of oppression but advances the proposition that the social organization of race, sexuality, gender and class are dependent on the sociohistorical context, time and place such that certain identities can become (at least momentarily) more salient than others (Dei, 1999; Nelson et al., 2014). The C4™ model centers the institutional nature of anti-Black racism and homophobia rooted in healthcare systems where many Black MSM must seek health services and it addresses anti-Black and heteronormative logics that manifest through the practices of healthcare workers (Hardeman et al., 2016; Mill et al., 2009).

Self-Determination Theory

The C4™ model is grounded in self-determination theory (SDT)—a social psychological theory of human motivation. SDT has a long history of use in health (Ng et al., 2012), but only recently used in HIV prevention research (Nelson et al., 2015). According to SDT, healthy behavior change is optimized in social environments that support three basic human psychological needs: autonomy, competence, and relatedness (Ryan & Deci, 2000). Autonomy is the need to behave based on one's own volition, which

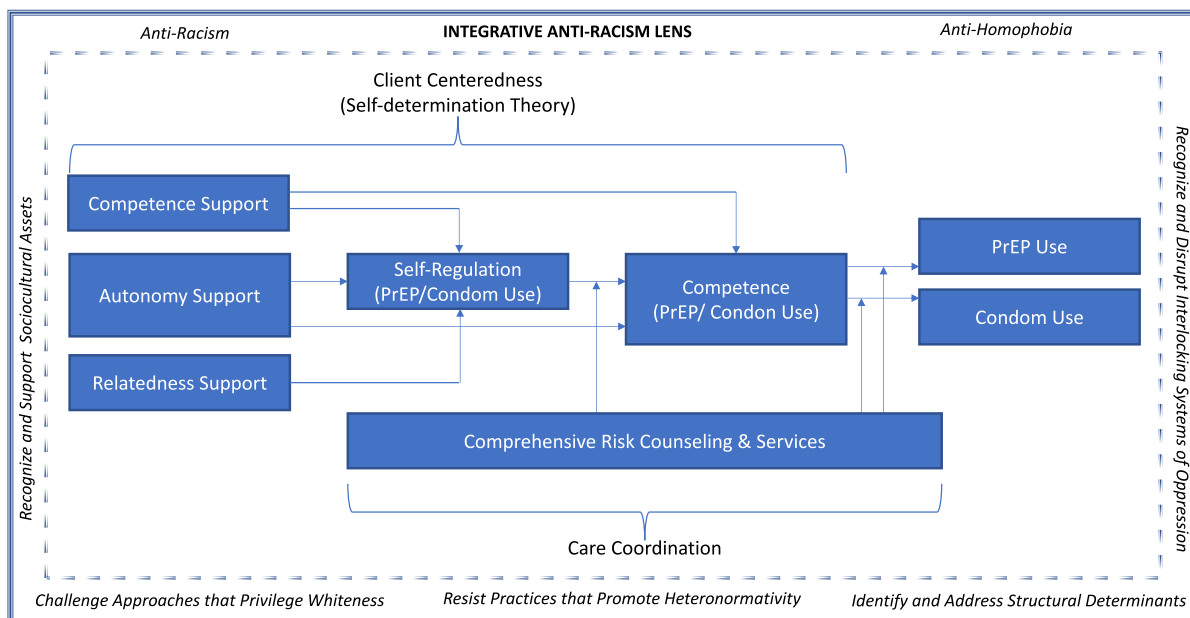


Fig. 1 Integrated theoretical and conceptual overview of client-centered care coordination

includes the potential for incorporating external input from key actors in social environments [competence and relatedness are discussed later in the paper] (Ryan & Deci, 2000). In C4TM, the healthcare setting is conceptualized as a social environment that influences health behaviors (e.g., medication adherence) and healthcare-seeking behaviors (e.g., HIV testing, STI testing, retention in care) of Black MSM. C4TM also considers the constituent members of those healthcare social environments (e.g., healthcare workers) to be key actors whose own attitudes and behaviors influence the overall social climate of the healthcare setting and may directly influence the behavior of clients with whom they come into contact. SDT's focus is simultaneously on the individual-level but also focuses on the attitudes and behaviors of the actors in the organizational-level setting where healthcare is delivered. Furthermore, SDT is asset-focused and grounded in the proposition that humans are naturally inclined to behave in ways that optimize their health and well-being and that these inclinations can be activated and nurtured through the support of basic motivational needs (Kennedy et al., 2004). SDT differs from traditional deficit-focused theoretical approaches to motivation that can otherwise compel short-term enactment of a target health behavior (Elder et al., 1999), at the expense of generating psychological distress, poor psychological well-being and internalized stigma. Thus, deficit-focused approaches are not sustainable for maintaining the target behavior over time—a critical issue in HIV prevention precisely because the protective effect of many strategies (e.g., condom use, oral and injectable PrEP) rely on the routine engagement of the behavior.

Conceptual Overview

Original Model: Comprehensive Risk Counseling and Services

Comprehensive risk counseling and services (CRCS) is a public health strategy that combines HIV risk reduction counseling with case management activities to address potential barriers to HIV prevention goal attainment (CDC, 2006). CRCS has been endorsed and widely disseminated through the CDC's Diffusion of Evidence-Based Intervention (DEBI) program. Its identification as a DEBI was an important criterion as it had an implementation strategy for local communities who were interested in adopting CRCS as part of their HIV prevention efforts. Nonetheless, neither the overall model nor its component activities were guided by a unifying theoretical framework. We therefore amalgamated self-determination theory and CRCS to guide the activities performed within the public health strategy, that involves the four components of (1) needs assessment, (2) behavioral counseling, (3) action planning, and (4) care coordination (inclusive of referrals, follow-up care, and planning

for transition off study and into community care) using an integrative anti-racism lens.

As previously discussed in this paper, SDT posits that people are naturally inclined to engage in behaviors that benefit their health (Ryan & Deci, 2000). This natural tendency can be activated through nurturance of an individual's basic motivational needs for autonomy (volition in decision-making), competence (accomplishing masteries needed to reach a behavioral goal), and relatedness (connection with the person who is caring for you) (Ryan et al., 2008). The activities derived from CRCS in the C4TM model are designed to support these three basic motivational needs. For example, participants were not required to take PrEP as a condition of study participation but could choose to initiate (or not initiate) PrEP at any time during the study period (Wheeler et al., 2019). This intentional study design reflects the principle of autonomy support from SDT. C4TM coordinators were also available to assist participants with various life needs that were not necessarily directly related to PrEP use (competence support)—demonstrating a connection and caring for the person's life beyond their adherence to a medication regimen (relatedness support). While SDT has only recently been used in HIV prevention research (Nelson et al., 2015), the efficacy of SDT-based intervention models has been firmly scientifically established in various other health domains (Ng et al., 2012). Furthermore, the overarching integrative anti-racism lens ensured that all activities and interactions responded to the pervasive interlocking nature of anti-Black racism and homophobia in the lives of the participants. Table 1 displays the activities in C4TM and their alignment and operationalization with SDT and integrative anti-racism.

Integrated Model: Client-Centered Care Coordination

The C4TM model is a multi-level, multi-component intervention model. The C4TM model includes the four components of CRCS (i.e., needs assessment, behavioral counseling, action planning, and care coordination; see also Table 1) that are integrated with an integrative anti-racism and SDT-based approach to counseling and client engagement. In addition to the client-focused component of C4TM, a key feature is its concurrent focus on assisting healthcare facility staff with understanding the ways in which they operate as part of the social setting that affects how clients are motivated to engage in targeted health behaviors, such as adherence to PrEP. This is unique from most interventions in HIV prevention for Black MSM—which focus solely on the individual as the target of attitudinal and behavioral change (K. T. Jones et al., 2008; Wilton et al., 2009). CRCS, for example, focuses on intensive behavioral counseling and case management of the clients. In contrast, the integration of SDT with CRCS

Table 1 Components of the client-centered care coordination intervention

Original CRCS component Examples of operationalization for client-centered care coordination (C4™)				
	Autonomy	Competence	Relatedness	Integrative anti-racism lens
Needs assessment	<p>All questions are optional. Client can decline to answer any question</p> <p>If client is reluctant to answer a question, explain the rationale for the question being asked</p> <p>Provide the client with an explanation of the limitation(s) of not knowing the answer</p> <p>Inform the client that if they do not wish to answer, you can explore options to ensure that they still receive the care that they seek</p>	<p>Ensure that client understands the questions that are being asked</p> <p>Support the clients in enhancing recall of historical information</p> <p>Assist the client in clarifying self-reported information in which the accuracy or relevance is uncertain</p>	<p>Be client-focused, not “form” focused</p> <p>Demonstrate interest in the information that the client is sharing. This may mean using “notes” to document elements of the client’s experience that are not included in pre-defined form fields</p>	<p>Reflect on any negative emotional reactions you are feeling towards the client’s needs. To what degree would you have the same reaction if these were expressed by: a White gay man? A Black straight man?</p>
Behavioral counseling	<p>The client decides what issue(s) they want to address</p> <p>The client is asked to self-identify impediments to their behavioral goal(s)</p> <p>The coordinator asks permission to identify possible impediments to goal attainment</p> <p>The client is encouraged to self-identify solutions</p> <p>Inform the client that they are free to reject any coordinator proposed solution</p>	<p>Express to the client that you believe in their ability to accomplish their agreed-upon goal(s)</p> <p>Collaborate with the client to assess reasonableness of behavioral goals, supporting aspirations while encouraging feasibility</p>	<p>Inform the client that you respect whatever decision they make and will be supportive of them in an ongoing process of them maintaining and/or improving the quality of their life</p>	<p>If the client is resistant, consider that it may be a response to a harmful history of anti-Black and homophobic experiences in systems that the client has had to rely on for “help.”</p> <p>Examine whether your “therapeutic approach” is reinforcing structural anti-Black and anti-LGBT violence by privileging solutions that center whiteness, respectability and heteronormativity</p>
Action planning	<p>Ensure the client is aware of all available options so they can make fully informed decisions about their action plan</p> <p>The client is encouraged to self-identify action steps</p> <p>The coordinator may propose action steps, but must defer to the preference of the client</p> <p>The coordinator may propose a priority sequence, but must defer to the preference of the client</p> <p>The client is the final decision-maker on what issues to prioritize for action</p>	<p>Assist the client in identifying strategies for implementing action steps</p> <p>Assist the client in anticipating actual and potential barriers to implementing action steps</p> <p>Assist the client in problem solving ways to overcome barriers to implementing action steps</p>	<p>Express respect for the client’s action plan</p> <p>Reassure the client that your primary role is to support their plan, not evaluate their performance</p> <p>Inform the client to be in touch with the coordinator if circumstances change so that they can work together to adapt the plan to new circumstances</p> <p>Inform the client that you what you have developed together is a plan, not a contract, and that you want to continue meeting with them regardless of the outcome of the plan</p>	<p>Imposing any component of a plan against the client’s wishes in an exercise of power and dominance.</p> <p>If you are inclined to “override” the client, quickly reflect on the white supremacist and homophobic logics that may underly how you justify your approach</p>

Table 1 (continued)

Examples of operationalization for client-centered care coordination (C4™)				
Original CRCS component	Autonomy	Competence	Relatedness	Integrative anti-racism lens
Care coordination	<p>Client determines what specific domains to apply care coordination support</p> <p>Client can decline any aspect of care coordination, including referrals</p> <p>Client should be informed of all available options, and allowed to choose (to the extent possible) the referral services that best meets their individual preferences</p>	<p>Assist the client in following up with referrals, including anticipating potential barriers to referral linkage and problem-solving how to address barriers, if encountered</p> <p>Directly intervene to bridge any disconnections between client and referral agency</p> <p>Provide feedback to client to assist in the self-management of future referrals</p>	<p>Try to address client needs, even if the needs are atypical for the coordinator's organization</p> <p>Inform the client that you will make a serious attempt, but that if your efforts are unsuccessful, you would inform them and will work with them to explore ways to get their needs met</p>	<p>Acknowledge the history of anti-Black racism and discrimination across all sectors of society—including in the referral agencies that may be involved in the care of the client</p> <p>Commit to following-up on any complaint of discrimination that the client reports—even if it is within your own organization. Accountability in integrative anti-racism work necessitates a willingness to advocate for justice notwithstanding the risk of punishment that can be imposed by institutions</p>

expanded it to a socioecological focus that also targets the behavior of the HCF staff in a way that both amplifies and sustains the effect of individual-level behavioral counseling and case management and that cannot otherwise be attained by focusing only on the individual.

Methodological Overview

C4™ was developed and implemented as part of the HIV Prevention Trials Network 073 (HPTN 073) PrEP demonstration project with Black MSM in three US cities (Los Angeles, CA; Washington DC; and Chapel Hill, NC). The aim of the study was to examine PrEP initiation and adherence among Black MSM who were offered once daily oral emtricitabine/tenofovir (FTC/TDF) PrEP combined with C4™ and followed up for 52 weeks. Participants also received HIV testing, risk reduction education and clinical monitoring. The HPTN 073 study protocol was reviewed and approved by institutional review boards of University of California at Los Angeles, The University of North Carolina at Chapel Hill and George Washington University. For more information on the outcomes of HPTN 073, see Wheeler et al. (2019). The purpose of this methodological overview is to describe the suite of measures that were used to assess the self-determination theory constructs (autonomy, relatedness, competence) and care coordination activities of C4™. The measures were collected at study visits scheduled across seven time points that were pre-specified in the protocol (i.e., enrollment and 4, 8, 13, 26, 39, and 52 weeks post-enrollment) and at unscheduled interim study visits.

Measures of Care Coordination

Care Coordination Measurement Log (CCML). We used a case report form (CRF) adapted from the care coordination measurement tool (Antonelli & Antonelli, 2004) to record the range and frequency of activities that were performed to organize the various aspects of the client's care needs. The CCML documented activities and characteristics related to care coordination of clients' needs such as amount of time spent on care coordination, focus of the care coordination encounter and outcomes resulting from care coordination effort. The form was completed by research study staff, who were specifically serving as care coordinators, to document their process of performing care coordination activities. For instance, staff documented information about the participant's sexual behaviors at the follow-up visit. They responded to questions such as "Was a sexual risk reduction referral recommended" and "Did the participant set a sexual risk reduction goal at this visit". Staff were instructed to complete the CCML for every care coordination activity for which more than five minutes of effort was required

to investigate and address. The CCML data were collected at any point throughout the 52-week study period to document any care coordination services provided to the clients, including at protocol scheduled study visits and unscheduled study visits.

Progress Towards Goals. At the 8-, 26-, and 52-week study visits, research staff who were assigned to provide counseling to the client used a CRF to rate their assessment of whether a client made progress towards the health goals set at the previous study visit. The progress assessment was done across three domains: PrEP adherence, sexual risk reduction, and substance use risk reduction. For example, “Did the participant make progress towards his PrEP adherence goal(s) set at the last study visit?” The CRF also included an option to note if a goal was not set at the last study visit. This was a qualitative assessment in which the rater was asked to consider the client's understanding of whether they have made progress and the rater's evaluation of any evidence that the client has made steps toward any goals that were set. The assessment was documented on a case report form as either “yes,” “no,” or “goal not set at last visit.”

Client Perception of Coordination Quality (CPCQ). The CPCQ measures an individual's self-assessment of how well healthcare related services are organized between multiple providers and organizations who are managing elements of their care. The 15-item questionnaire covers four domains of care coordination: (1) satisfaction with services, (2) quality of care coordination received, (3) coherence and complication of coordination, and (4) impact of coordination of client capacity (McGuinness et al., 2003). Individuals were asked to indicate how often they received the service indicated using a 5-point Likert-type scale from “1 = never” to “5 = always.” Sample items include: “How often were you confused about the roles of different providers”, “How often did you get the services you thought you needed” and “How often did you get conflicting advice from providers.” Items that indicate poor care coordination were reverse coded and the overall questionnaire is scored by calculating the mean of all 15-items. The internal consistency of the CPCQ was 0.84 in this sample. CPCQ data were collected at the 8-, 13-, 26-, and 52-week study visits.

Measure of Self-Determination Theory

Healthcare Climate Questionnaire. The healthcare climate questionnaire (HCCQ) is a 15-item scale (ranging from 1 = strongly disagree to 7 = strongly agree) assessing autonomy, competence, and relatedness supports (Nelson et al., 2015; Williams et al., 1999; Williams et al., 2006; Williams et al., 1998). The HCCQ assesses the degree to which participants experience that their basic psychological needs for autonomy, competence, and relatedness were fulfilled in

interactions with their healthcare providers. HCCQ allowed us to determine if participants had healthcare experiences that were optimized for HIV prevention, including PrEP adherence. Participants responded to questions such as “I feel that my healthcare team has provided me choices and options,” “I feel understood by my healthcare team,” and “I am able to be open with my healthcare team at our meetings.” Responses were averaged and higher scores indicate greater autonomy support. The internal consistency for the HCCQ was 0.96 in this sample. HCCQ data were collected at all protocol scheduled study visits, except the enrollment visit.

PrEP Self-Regulation Questionnaire. The PrEP-SRQ is a 15-item scale (ranging from 1 = not all true to 7 = very true) that assesses the participants' motivations for using HIV PrEP. The SRQs are composed of three validated subscales that assess for various forms of motivation on a continuum from amotivation (e.g., “I don't know why I use PrEP”), to external motivation (e.g., “I used PrEP because I would feel guilty if I didn't”) and internalized motivation (e.g., “I use PrEP because it fits with my life goals”). It is a modification of the treatment self-regulation questionnaires that have been used in a variety of health studies, including randomized controlled trials (Levesque et al., 2007). For HPTN 073, the stem of the SRQ items remained the same (i.e., “The reason I would use PrEP is_____”), while the form of motivation was revised to reflect indicators of PrEP self-regulation. Participants were asked to respond to reasons why they use PrEP, such as “Because I feel that I want to take responsibility for my own health,” and “Because I would feel bad about myself if I did not.” Responses were averaged and higher scores on SRQs are associated with increased odds of engaging in the target health behavior over the short term and maintenance of the behavior over the long-term. The internal consistency for the PrEP-SRQ was 0.95 in this sample. PrEP- SRQ data were collected at all protocol scheduled study visits.

Condom Self-Regulation Questionnaire. The Condom-SRQ is a 15-item scale (ranging from 1 = not all true to 7 = very true) that assesses the participants' motivations for condom use. The SRQs are composed of three validated subscales that assess for various forms of motivation on a continuum from motivation (e.g., “I don't know why I use a condom”), to external motivation (e.g., “I used a condom because I would feel guilty if I didn't”) and internalized motivation (e.g., “I use condoms because it fits with my life goals”). It is a modification of the treatment self-regulation questionnaires that have been used in a variety of health studies, including randomized controlled trials (Levesque et al., 2007). For HPTN 073, the stem of the SRQ items remained the same (i.e., “The reason I would use condoms is_____”), while the form of motivation was revised to reflect indicators of condom use self-regulation. Participants were asked to respond to reasons why they use

condoms, such as “Because it is easier to do what I am told than think about it,” and “Because I have carefully thought about it and believe it is very important for many aspects of my life.” Responses were averaged and higher scores on SRQs are associated with increased odds of engaging in a target health behavior and the long-term maintenance of the target behavior. The internal consistency of the condom-SRQ was 0.95 in this sample. Condom-SRQ data were collected at all protocol scheduled study visits.

Perceived Competence for PrEP Use. This 4-item scale (ranging from 1 = not all true to 7 = very true) measured an individual’s assessment of the degree to which they felt competent to master or accomplish the task of daily oral PrEP and was adapted from the Perceived Competency Scale (PCS) (Williams & Deci, 1996). Participants were asked to rate, as either true or false, statements regarding their ability to adhere to a daily oral PrEP regimen, such as “I feel confident in my ability to use PrEP daily, as recommended,” and “I am capable now of handling using PrEP daily.” Perceived competence is a key component of measuring self-determination theory in conjunction with companion scales that measure autonomy support (Williams & Deci, 1996; Kennedy et al., 2004). In previous studies, higher scores on the PCS were associated with increased odds of adherence to diabetic treatment plan (Williams et al., 1998) and adherence to antiretroviral medication (Kennedy et al., 2004). Responses were averaged and the internal consistency 0.84 for the PCS-PrEP Use. PCS-PrEP Use data were collected at all protocol scheduled study visits, except the enrollment visit.

Perceived Competence for Condom Use. This 4-item scale (ranging from 1 = not all true to 7 = very true) measured an individual’s assessment of the degree to which they feel competent to master or accomplish a specific the specific task of using condoms during sex. It was also adapted from the Perceived Competency Scale (PCS) (Williams & Deci, 1996). Participants were asked to rate, as either true or false, statements regarding their ability to use condoms consistently, such as “I feel confident in my ability to use condoms every time I have sex,” and “I am capable now of using condoms every time I have sex.” Perceived competence is a key component of measuring self-determination theory in conjunction with companion scales that measure autonomy support (Williams & Deci, 1996; Kennedy et al., 2004). Responses were averaged and the internal consistency 0.80 for the PCS-Condom Use. PCS-Condom Use data were collected at all protocol scheduled study visits, except the enrollment visit.

Analysis

We used data collected on the CCML to calculate the mean number of care coordination encounters per study site (Chapel Hill, NC; Los Angeles, CA; and Washington DC). We also used CCML data to calculate the proportions of the study visit that were dedicated to specific encounters at each of the three study sites. Proportions were also calculated to summarize the number of participants who were classified as having made progress towards their goals in three domains: PrEP use, sexual risk reduction and substance use risk reduction. For each study visit, we calculated the means for the HCCQ, PrEP SRQ, Condom Use SRQ, PCS-PrEP use, PCS-Condom Use and the CPCQ. We used the Wilcoxon sign-ranked test to compare mean scores on the SDT-indicator variable across study visit time points.

Results

Sample Characteristics

The detailed characteristics of the participants enrolled in HPTN 073 are previously described (Wheeler et al., 2019). In summary, of the 226 participants enrolled, 85% reported identifying as Black only, more than half (60%) were older than 25 years old, two-thirds had at least some college education, and 48% had an annual income as less than \$20,000.

Care Coordination

Over the course of the study, there were a total of 1135 care coordination encounters. Engagement in [care coordination](#) varied across sites with an average of 5.0 ($SD = 2.8$) encounters per participants. Participants in the Washington DC site had the highest number of encounters per participant with a mean of 7.3 ($SD = 1.7$). PrEP adherence support services accounted for almost half (43.3%) of all care coordination activities across sites, followed by sexual health services (19.1%), and social services (14.8%) as the most frequent focus of care coordination activities. The least frequent foci of care coordination activities were linkage to HIV care services and legal/judicial services which combined comprised only 1.2% of all care coordination activities provided. Table 2 outlines the total frequencies of care coordination activities by site.

Care coordination activities led to a variety of care coordination outcomes (Table 3). Overall, a majority (59.5%) of the care coordination activities led to the client’s immediate needs being met across all sites. Ordering prescriptions,

Table 2 Number and proportion of client-centered care coordination encounter, by site

Care coordination activity	Total (<i>N</i> =1135)	Study site		
		Los Angeles, CA (<i>n</i> =377)	Chapel Hill, NC (<i>n</i> =212)	Washington DC (<i>n</i> =546)
Mean number of C4 encounters per participant (SD)	5.0 (2.8)	5.0 (2.7)	2.8 (1.6)	7.3 (1.7)
Focus of C4 encounter (% of total encounters)				
PrEP adherence support	492 (43.3)	179 (47.2)	65 (30.7)	249 (45.6)
Sexual health services	217 (19.1)	76 (20.2)	35 (16.5)	106 (19.4)
Social Services (e.g., housing, food, clothing)	168 (14.8)	43 (11.4)	21 (9.9)	104 (19.0)
Clinical/medical management	67 (5.9)	21 (5.6)	38 (17.9)	8 (1.5)
Mental health	52 (4.6)	20 (5.3)	22 (10.4)	10 (1.8)
Substance use treatment	47 (4.1)	18 (4.8)	6 (2.8)	23 (4.2)
Employment	40 (3.5)	2 (0.5)	1 (0.5)	37 (6.8)
Referral management	39 (3.4)	12 (3.2)	19 (9.0)	8 (1.5)
Linkage to HIV care	10 (0.9)	6 (1.6)	3 (1.4)	1 (0.2)
Legal/judicial	3 (0.3)	1 (0.3)	2 (0.9)	0 (0)

supplies, and services (10.9%), referrals to community agencies (9.3%), lab reviews (7.8%), and referrals to a primary care physician (5.1%) accounted for the remaining care coordination outcomes. The distribution of key indicators over the 12-month study period are presented in Table 4. Averaged across all three study visits where participants were invited to set behavioral goals (baseline, 8-week, 26-week) the largest proportion of goals set were for sexual risk reduction (94%), followed by PrEP adherence (73%) and substance use risk reduction (16%). Similarly, larger

proportions of goal setters made progress towards attaining sexual risk reduction (88%) and PrEP adherence (80%) goals, compared to substance use risk reduction goals (72%).

Care coordination quality was assessed at the week 8 study visit and every visit thereafter. Mean scores on the CPCQ were above average at every study visit, with the lowest mean score of 3.92 (*SD*=0.31) at the week 8 visit—the first visit at which care coordination quality was assessed (Table 4). Care coordination quality did not vary widely over time, with the largest difference (+0.39) occurring between

Table 3 Number and proportion of client-centered care coordination outcomes occurred

Care coordination outcomes	Total (<i>N</i> =1700)			Los Angeles, CA (<i>n</i> =808)			Chapel Hill, NC (<i>n</i> =294)			Washington DC (<i>n</i> =598)		
	<i>a</i>	<i>b</i>	<i>c</i>	<i>a</i>	<i>b</i>	<i>c</i>	<i>a</i>	<i>b</i>	<i>c</i>	<i>a</i>	<i>b</i>	<i>c</i>
Client's immediate need(s) met	1011	89.1	59.5	326	86.5	40.5	144	67.9	49.0	541	99.1	90.5
Order prescriptions, supplies, services	186	16.4	10.9	184	48.8	22.8	2	0.9	0.7	0	0	0
Referral to community agency	158	13.9	9.3	74	19.6	9.2	66	31.1	22.4	18	3.3	3.0
Reviewed labs, specialist reports	133	11.7	7.8	119	31.6	14.7	7	3.3	2.4	7	1.3	1.2
Referral to primary care provider	86	7.6	5.1	51	13.5	6.3	29	13.7	9.9	6	1.1	1.0
Advocacy for client/family	34	3.0	2.0	28	7.4	3.5	0	0	0	6	1.1	1.0
Referral to specialist	33	2.9	1.9	8	2.1	1.0	11	5.2	3.7	14	2.6	2.3
Referral to specialized therapies	17	1.5	1.0	13	3.4	1.6	3	1.4	1.0	1	0.2	0.2
Outcome pending	15	1.3	0.9	5	1.3	0.6	10	4.7	3.4	0	0	0
Referral to lab/x-ray	14	1.2	0.8	0	0	0	14	6.6	6.8	0	0	0
Reconciled discrepancies	10	0.9	0.6	0	0	0	8	3.8	2.7	2	0.4	0.3
Advised client/family home management	3	0.3	0.2	0	0	0	0	0	0	3	0.5	0.5

^acount

^b% of total encounters

^c% of total care coordination outcomes occurred

Table 4 Distribution of key indicators over 12-month study participation period ($N=225$)

Measure		Week number						
		Baseline ($N=225$)	4 ($n=209$)	8 ($n=203$)	13 ($n=206$)	26 ($n=202$)	39 ($n=189$)	52 ($n=206$)
Healthcare Climate Questionnaire $M(SD)$	—		6.23 (1.09)	6.35 (0.89)	6.21 (1.02)	6.09 (1.22)	6.13 (1.24)	6.10 (1.30)
Self-regulation questionnaires								
	Condom use $M(SD)$	4.06 (0.97)	4.08 (0.91)	4.04 (0.91)	4.14 (0.98)	3.82 (0.99)	3.99 (1.13)	3.85 (1.08)
	PrEP use $M(SD)$	3.27 (0.89)	3.45 (0.92)	3.46 (0.82)	3.59 (1.01)	3.53 (0.97)	3.50 (1.03)	3.49 (1.04)
Perceived competence								
	Condom use $M(SD)$	—	5.79 (1.52)	5.74 (1.52)	5.75 (1.49)	5.43 (1.68)	5.44 (1.82)	5.33 (1.91)
	PrEP use $M(SD)$	—	5.95 (1.38)	5.81 (1.56)	5.81 (1.55)	5.69 (1.71)	5.48 (1.94)	5.53 (1.78)
Long-term PrEP adherence								
	% of people who set goals set at last visit	—	—	75%	—	76%	—	67%
	% of goal setter making progress towards adherence goals	—	—	83%	—	75%	—	81%
Sexual risk reduction								
	% of people who set goals set at last visit	—	—	91%	—	95%	—	95%
	% of goal setter making progress towards sex risk reduction goals	—	—	91%	—	84%	—	88%
Substance use risk reduction								
	% of people who set goals set at last visit	—	—	18%	—	16%	—	13%
	% of goal setter making progress towards sex substance use risk reduction goals	—	—	69%	—	77%	—	69%
Client perception of coordination quality $M(SD)$	—	—	—	3.92 (0.31)	4.31 (0.63)	4.34 (0.64)	4.32 (0.66)	4.35 (0.65)

HCCQ healthcare climate questionnaire, SRQ self-regulation questionnaire

week 8 and 13. The mean scores between the remaining visits ranged from 4.31 ($SD=0.63$) at week 13 to 4.35 ($SD=0.65$) at week 52; however, there were no statistically significant differences in [care coordination](#) quality between any two time points during the study period.

Self-Determinant Theory Indicators

Healthcare Climate Questionnaire-HCCQ. The mean scores for the HCCQ are presented in Table 4. The mean scores on the HCCQ ranged from 6.09 to 6.35 throughout the study period. While the mean scores fluctuated over time, these were not statistically significant changes and the scores all remained above an agree (6) rating for healthcare climate at all time points.

Self-regulation. The mean scores for the SRQ – Condom Use and PrEP use measures are reported in Table 4. The mean scores on the condom use self-regulation measure ranged from 3.82 to 4.14 over time. The mean scores on the PrEP use self-regulation ranged from 3.27 to 3.59 over the 52 weeks. The mean scores on the self-regulation for condom use measure coalesced around the median rating of somewhat true (4) but decreased slightly over time. There were no statistically significant changes in the scores in SRQ scores for condom use or PrEP.

Perceived Competence. The mean scores for perceived competence for condom and PrEP use are reported in Table 4. The mean score on the perceived competence for condom use range from 5.33 to 5.79 over the study period. The mean scores for perceived competence for PrEP use

ranged from 5.48 to 5.95 during the study. The mean scores for perceived competence remained above the median rating (4—somewhat true) over the study timeframe, with no statistically significant differences between study time points.

Discussion

Our objective was to provide theoretical, conceptual, and methodological descriptions of C4™ and its implementation in HPTN 073. C4™ was developed through the integration of SDT with the CRCS public health strategy utilizing an integrative anti-racism lens. C4™ is a novel care model based on the tenants of SDT: the innate motivations of humans and engagement that supports autonomy and informed decision-making regarding sexual risk reduction practices. The coordination component of C4™ is an extension of the competence and relational constructs in SDT. The relational component involves displaying genuine concern for the clients' needs and making serious attempts to help them fill those needs that they identified as important. The addition of C4™ addresses the gaps in existing interventions (the lack of incorporating structural factors, deficit-based models, does not recognize the importance of racism in healthcare provisions for Black MSM). This approach is unique from traditional case management or patient navigation models for individual level HIV prevention services (Katz et al., 2001). Traditional HIV case management and patient navigation programs are designed to address pre-determined goals and coordinate the access of services through referrals to social services and community organizations (Ko et al., 2013). C4™ differs from these models because it focuses on influencing the behavior of the case manager/coordinator to support the client's motivational needs for autonomy, competence and relatedness. C4™ directly attends to the issue of structural and institutional racism within systems and attempts to minimize the barriers associated with anti-Black racism for the client.

We observed that the frequency of care coordination visits between sites differed, with a higher number of care coordination encounter in Washington DC ($n = 546$) compared to Los Angeles ($n = 377$) or Chapel Hill ($n = 212$). This occurred even though each site enrolled approximately equal numbers of participants. Additionally, despite the higher frequency of care coordination encounters in Washington DC, the distribution of the focus of the encounters mirrored the other two sites. In all three sites the most C4™ encounters were conducted for PrEP adherence support and sexual health services—representing 67% of C4™ encounters in Los Angeles, 65% of encounters in Washington DC and 47% of encounters in Chapel Hill. This indicates that although there were site specific differences in the frequencies of encounters, overall, the distribution of foci was

similar across sites. Similarly, social service needs were the third most frequent focus of C4™ visits in Los Angeles (11%) and Washington DC (19%); however, Chapel Hill was the only site where the third most frequent focus on C4™ visits was for clinical/medical management (18%). This indicates that these participants in the Chapel Hill site had more difficulties getting their clinical/medical needs met. We surmise that this is an artifact of differences in the health-care policy environments between North Carolina which has not adopted Medicaid expansion under the Affordable Care Act and the other two sites where Medicaid expansion has been adopted—likely contributing to reductions in barriers to Black MSM in those communities getting their medical needs met. This also highlights the patterns of C4™ use and effectiveness will likely be influenced by the local healthcare policy environment and the availability of services and other resources for meeting clients' needs. Nonetheless, despite the complexities of the clients' needs, previous published reports on C4™ implementation provided evidence that it is a relatively low-intensity model with clients receiving an average of five care coordination encounters over a 12-month period (Whitfield et al., 2021). The average length of the care coordination encounters was 30 min. The C4™ model has also been shown to be relatively low-cost, with the mean cost-per encounter of \$8.70 (Whitfield et al., 2021). Moreover, the majority (96%) of the C4™ encounters were handled by counselors at a per-encounter cost (\$8.30) that was substantially less than that of licensed professional personnel, including registered nurses (\$21.30; +61%), social worker (\$19.20; +57%), physician assistant (\$16.30; +49%) and nurse practitioner (\$16.00; +48%) (Whitfield et al., 2021). This evidence complements data from the current study by highlighting that even though C4™ is designed to accommodate complex psychosocial and structural realities, it does not place high demands on staff time or add substantial costs to program operations, both of which are key implementation determinants (Damschroder et al., 2009; Smith et al., 2020) that organizations consider when deciding whether to incorporate an intervention into their practice.

In HPTN 073, there were stark differences between the three communities in the proportion of care coordination encounters that resulted in the client's immediate needs being met. In Washington DC, 99.1% of care coordination encounters resulted in the client's immediate needs being met compared to Chapel Hill (68%) and Los Angeles (87%). Additionally, “the clients' immediate need(s) met” represent 91% of the care coordination outcomes in Washington DC, even though it represented less than half of the care coordination outcomes in Chapel Hill (49%) and Los Angeles (40%). These differences may be reflective of differences in availabilities of local resources for coordinators to leverage in meeting the clients' needs. These observed differences are also likely to have been heavily influenced by the proportional

differences in individual-level material resources for the clients. For example, a previous report on HPTN 073 (Wheeler et al., 2019), indicated that the sub-sample in Washington DC had higher proportion of participants who had incomes of \$40,000 or more (52%) compared to Chapel Hill (15%) and Los Angeles (13%). The Washington DC sample also had higher proportions of people who were college educated (43% DC vs 30% Los Angeles v 29% Chapel Hill) and who had healthcare insurance (80% in DC vs 63% in Los Angeles and Chapel Hill). It is also noted that Los Angeles was the community where “client’s immediate need(s) met” represented the smallest proportion of care coordination outcomes (41%). This may also reflect differences in the social realities in the Los Angeles sample. In HPTN 073, Los Angeles had a greater proportion of the sample with a history of incarceration which likely introduces other complexities into the ability of care coordinators to meet client’s needs for issues such as housing and employment which often have restrictions imposed for individuals with incarceration histories. These complexities may have been less prevalent in the Washington DC with as much smaller proportion of men who had been previously incarcerated (Wheeler et al., 2019). These findings are corroborated by evidence from a previous study of with Black MSM in six US cities (Nelson et al., 2016).

In this study, participants in C4TM experienced high levels of autonomy support in their healthcare decision-making. As one of the pillars of SDT is the autonomy in decision-making, the high level of participants reporting autonomy support suggest a major component of the study design was achieved by the model. We did not observe statistically significant changes in any of the SDT indicator variables. HPTN 073 was not hypothesis testing any of the SDT indicator variables and thus the study was not powered to detect statistical differences between care coordination visit time points. The SDT indicator variables were included for observational purposes in order to longitudinally monitor the distribution of SDT indicator scores. These findings suggest participant’s motivation for using PrEP remained stable and became more internalized over time—which is consistent with SDT. These findings align with other studies which found that focusing on internal motivation led to adopting HIV prevention behaviors (Aliabadi et al., 2015; Golub et al., 2013; Kalichman et al., 2008). Golub et al. found motivation for PrEP use was a strong predictor of short and long-term PrEP use among cisgender MSM and transgender women in New York City (2013). Our findings that there was no change in condom use self-regulation over time are consistent with clinical trials of PrEP and condom use behavior (Liu et al., 2013; Marcus et al., 2013) which found no change in condom use with the introduction of PrEP. Nonetheless, our study examined the motivation for condom use over time while the above-cited studies assessed actual condom use

over time. The observation that there were no changes in condom use self-regulation scores among HPTN 073 participating does not suggest that condom use behavior did not change; it means that the reasons motivating condom use (or nonuse) during sex did not change over time. Even still, our findings contrast with other studies which found changes in condom use motivation after PrEP initiation (Gamarel & Golub, 2015; Montano et al., 2019; Paz-Bailey et al., 2016). For example, Gamarel & Golub (2015) found intimacy motivations were associated with PrEP use and increase in condomless anal sex among MSM. Our study findings are not directly related to PrEP use or condom use behaviors but the self-regulation of these behaviors. These findings may suggest participants had a stable experience of heightened autonomy to choose which risk reduction strategies made the most sense for their lives, highlighting one of the key SDT-focused components of C4TM; supporting the autonomy of participants to make decisions about their sexual health behavior (Nelson et al., 2015; Ng et al., 2012).

Our finding that perceived competence for condom use did not change during the study period counters evidence from previous research which suggests continued engagement in HIV prevention activities lead to increased competence and self-efficacy (Forsyth & Carey, 1998; Kang et al., 2004). Yet, these findings may allude to the role of contextual factors associated with perceived competence. As previously stated, perceived competence arises from motivation that one can do a good job at accomplishing a behavioral goal (Ryan & Deci, 2000; Rodgers et al., 2014). As indicated by Maslow (1970), psychological needs are met once basic pre-requisite social and material needs are fulfilled. The consistency in perceived competence scores in the sample may be related to unfulfilled basic social and material needs. Further research should focus on the role of perceived competence and social determinants of health in HIV prevention among Black MSM (Chu et al., 2020; Hightow-Weidman et al., 2017; Mayer et al., 2014).

Goal setting was something that nearly all participants did, even though it was optional. The majority of goal setters across all three behavioral domains assessed (PrEP adherence, sexual risk-reduction, substance use risk-reduction) made progress towards meeting their goals. The goal setting process was collaborative between the participants and the C4TM coordinator and emphasized feasibility—that is, participants received coaching and feedback to help them identify and set behavioral goals that were sufficiently challenging, but that could be achieved with adequate care coordination resources. Goal setting is consistent with SDT to the extent that the goal is volitional (autonomy support) and that there are sufficient resources provided to assist the client in attaining the goal (competence support). The autonomy support approach also includes the provision of non-punitive feedback (competence support) and unconditional positive

regard (relatedness support). The provision of autonomy support, competence support and relatedness support were provided at every study visit and was not contingent on the participant making progress towards achieving the goals (Ng et al., 2012; Ryan & Deci, 2000; Williams et al., 2006). A recent meta-analysis of 384 effect sizes from 141 studies found that goal setting has a statistically significant effect on behavior ($d=0.34$, 95% CI: 0.28, 0.41) and that it was particularly effective for health behaviors ($d=0.44$, 95% CI: 0.31, 0.56) (Epton et al., 2017). The appraisal of goal progress by the C4TM coordinator is an important component given the evidence that provision of external monitoring was a statistically significant moderator of goal setting on behavior ($\beta=0.60$, $p<0.001$) (Epton et al., 2017). Goal setting and progress appraisal with a coordinator also helps to ensure congruence between the goal and the planned activities to attain it which has also been shown to improve the effectiveness of goals on behavioral outcomes (Epton et al., 2017). Future research may consider whether goal setting and externally appraised progress toward goal attainment predicts PrEP adherence, condom use, or substance use among Black MSM (Ezennia et al., 2019; Ogbuagu et al., 2019; Storholm et al., 2017). Such evidence could inform the leveraging of goal-oriented approaches to optimize existing HIV prevention interventions.

Limitations

There are several important limitations to the model that deserve mention here. First, C4TM is an adaptation a previous model that was not designed specifically to take into account the social realities of people who are racialized (e.g., Black) or sexualized (e.g., gay) into “minority” groups. Further, the model uses theory to both organize and justify the types and sequence of intervention activities. These two important adaptations substantially differentiate the C4TM model from its CRCS progenitor. There is current scholarly debate regarding whether this would constitute an adaptation or whether it is more appropriately characterized as a reinvention (Ansari et al., 2010; Kalichman et al., 2010). The evidence-base on intervention re-invention is not well-established in the HIV research literature; however, references to re-invention generally characterize it as something to be avoided in favor of modest modifications that do not alter core features or logics of the original intervention (Kalichman et al., 2010). In this case, the scarcity of interventions that addressed the social and structural forces that impede HIV prevention for Black MSM rendered “modest modifications” as an insufficient approach to adaptation and instead favored a re-invention that salvaged the most useful components of the original model. While the selection of an integrative anti-racism lens is a novel approach to guiding

client-centered care coordination, it has not previously been used to guide HIV prevention intervention research. Additional studies that apply an integrative anti-racism lens are needed to further determine evidence of its robustness and stability as a concept for use in HIV prevention. Third, the C4TM model was adapted with the specific realities of Black MSM in mind. Translating the model for use with other populations including women (cisgender and transgender women), adolescents and other social marginalized communities may necessitate additional intersectional theorizing that integrates feminist, queer, human development, class-based, social justice and other concepts. Nonetheless, the theoretical components in which C4TM is grounded have been applied to multiple health domains across multiple populations (Ng et al., 2012). Fourth, we did not find any statistically significant differences in SDT indicators between the study visit time points. It is important to note that although we do not have evidence to reject the null hypothesis that SDT indicators changed over time, we did not test a specific directional SDT-derived hypothesis. Future analyses of the HPTN 073 study should subject those data to hypothesis testing analyses that investigate relationships and theoretical pathways between C4TM and key clinical (e.g., HIV infection, sexually transmitted infections) and behavioral (e.g., PrEP adherence, condomless anal intercourse) outcome variables. Finally, the model has not been tested for definitive efficacy in a randomized controlled trial. Future research that examines the efficacy and implementation of C4TM has the potential to lead to important simultaneous advances in HIV prevention science and accelerated progress toward ending the domestic US HIV epidemic.

Conclusion

C4TM is a multi-level, multi-component intervention model that dually targets the individual-level motivations and capacities of Black MSM as well as the organization/provider-level attitude and behaviors that shape the climate of the healthcare environment where Black MSM receive care. It is a low-intensity model where, although the care coordination component of the model was designed to accommodate a broad range of psychosocial needs, participants in HPTN 073 primarily used it to address needs related to PrEP adherence. Moreover, the vast majority of care coordination encounters resulted in the client’s immediate needs being met. C4TM is an important prevention tool that is built on a sound theoretical framework. Public health policy efforts to scale-up PrEP with Black MSM may consider C4TM as a tool to optimize the use of PrEP and PrEP program retention. The public health implementation of C4TM has already begun in several communities that have integrated its use into state and local efforts to

reduce HIV incidence among Black MSM, such as the New York State Department of Health AIDS Institute's End the Epidemic initiative. Lastly, C4™ can be used in conjunction with other interventions within the nation's prevention toolkit including with behavioral interventions and can also be used to facilitate the uptake and prevention impact of newer biomedical products for PrEP, such as currently available long-acting injectable forms (Landovitz et al., 2021) and future potential long-acting oral regimens (Grobler et al., 2017).

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Data Availability The data is publicly available from the HIV Prevention Trials Network at https://www.hptn.org/resources/concept_ancillarystudy.

Code Availability Not applicable.

Declarations

Conflict of Interest C4 is a trademark of tuliptree systems, LLC. The first author is a shareholder and officer of tuliptree systems, LLC. The first author was neither involved in the recruitment of study participants nor in obtaining informed consent.

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