PI: Sophia Hussen MD, MPH
IRB 00088255
Assistant Professor, Emory University
[redacted]

Social Capital and Engagement in Care Among Young Black Men who have Sex with Men Living with HIV

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Rollins School of Public Health
Emory University
1518 Clifton Rd NE
Hubert Department of Global Health

PRINCIPAL INVESTIGATOR
Sophia Hussen, M.D., M.P.H.
Assistant Professor of Public Health and Medicine

MENTORS/ CO-INVESTIGATORS:
Andres Camacho-Gonzalez, MD, MSc
Assistant Professor of Pediatrics

Carlos del Rio, MD
Professor of Public Health and Medicine

KEY COLLABORATOR:
Gary W. Harper PhD, MPH
Professor of Public Health (University of Michigan)

PROJECT COORDINATOR
Marxavian Jones, MPA

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LIST OF ABBREVIATIONS AND ACRONYMS

ACASI: Audio computer assisted survey instrument
AIDS: Acquired Immune Deficiency Syndrome
ARV: Antiretroviral medications
ART: Antiretroviral Therapy
CBO: Community-Based Organization
CDC: Centers for Disease Control and Prevention
CFAR: Center for AIDS Research
EMR: Electronic Medical Record
HCW: Health Care Worker
HIPAA: Health Insurance Portability and Accountability Act
HIV: Human Immunodeficiency Virus
IDI: In-depth Interview
IDP: The Grady Infectious Disease Program
IOM: Institute of Medicine
LGBT: Lesbian, Gay, Bisexual and Transgendered
MACARTI: Metropolitan Atlanta Community Adolescent Rapid Testing Initiative
MARI: Minority AIDS Research Initiative
MARTA: Metropolitan Atlanta Rail Transit Authority
MSCS: Modified Social Capital Scale
MSM: Men who have sex with Men
REDCAP: Research Electronic Data Capture
RCT: Randomized Controlled Trial
YBMSM: Young Black Gay, Bisexual and Other Men who have Sex with Men
YCAB: Youth Community Advisory Board

PROJECT OVERVIEW

TITLE: Social Capital and Engagement in Care among Young Black Men who have Sex with Men Living with HIV

PROTOCOL SUMMARY: Young black gay, bisexual and other men who have sex with men (YBMSM) have high rates of HIV acquisition and low rates of healthcare utilization. Innovative interventions are urgently needed to improve engagement in care in this population. We propose a study focused on understanding and augmenting social capital among YBMSM with the ultimate goal of positively impacting engagement in HIV care. There are three phases to this study. Phase I: A mixed methods exploration of social capital including qualitative interviews and analysis of previously collected survey data, leading to development of a social capital intervention. Phase II: A randomized controlled trial of groups of YBMSM implementing the social capital intervention versus groups of YBMSM receiving a general health promotion intervention (Health for Life; H4L). Phase III: Follow up measurements of social capital and engagement in care with the HIV-positive YBMSM at 1 month, 4 month, and 10 month timepoints. We plan to enroll 180 total participants (120 in the randomized controlled trial and 60 in preliminary interviews) over the four year study period.

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RESEARCH TEAM AND COLLABORATORS

Name	Degree (s)	Role on Project/Tasks	Institution
Sophia Hussen	MD, MPH	Principal Investigator -lead all aspects of study activities, data security, analyses and dissemination	Emory University
Andres Camacho-Gonzalez	MD, MSc	Mentor/Co-Investigator -local senior mentor; provides scientific guidance and support	Emory University
Carlos del Rio	MD	Mentor/Co-Investigator -local senior mentor	Emory University
Gary Harper	PhD, MPH	Key Collaborator -community-based participatory research expertise	University of Michigan
Marxavian Jones	MPA	Research Interviewer/Interventionist -study coordinator, recruiter, group facilitator, -manage day-to-day aspects of research activities	Emory University
Jasper Hood	BA	Recruiter, Research Interviewer	Emory University
Shamia Moore	MPH	Research Interviewer -process evaluation	Emory University
Madeline Sutton	MD, MPH	Scientific Mentor -CDC support and mentorship	Centers for Disease Control and Prevention
Ashley Murray	MPH	Project Officer -CDC support and guidance	Centers for Disease Control and Prevention

Ms. Ashley Murray is the CDC project officer and will be providing technical support only. She will not directly engage with study participants, nor have access to identifiable data. Therefore, CDC is considered not engaged in this study.

Dr. Madeline Sutton is the CDC scientific mentor and will be providing technical support only. She will not directly engage with study participants, nor have access to identifiable data. Therefore, CDC is considered not engaged in this study.

1.1 INTRODUCTION

1.2 Literature Review

1.2.2 Epidemiology of HIV among young Black men who have sex with men: Young Black gay, bisexual and other men who have sex with men (YBMSM) are being diagnosed with HIV at increasing rates, more than any other demographic or risk group category in the United States.[1] Between 2006 and 2009, HIV incidence among YBMSM increased by 48%, which was the largest increase seen in any population subgroup.[1] Effective interventions to improve HIV treatment and prevention among YBMSM are urgently needed.[2] The "Test and Treat" approach, which promotes rapid initiation of antiretroviral medications (ARVs) soon after diagnosis, is now accepted as the standard of clinical care; and "Treatment as Prevention" is similarly gaining traction in the field of HIV prevention, as population-based studies clearly demonstrate a decrease in HIV transmission with widespread uptake and utilization of ARV use.[3,4] However, these proven strategies can only be effective in the context of optimized engagement in medical care. Given that YBMSM make up an increasing proportion of HIV-positive patients entering care, it is critically important to characterize and understand influences on engagement within this specific population.

***1.2.3 Continuum of Engagement in HIV Care*:** Engagement in HIV care has been conceptualized as a continuum with the following stages: (1) HIV diagnosis, (2) Linkage to care, (3) Retention in care, (4) Initiation on, and adherence to, ARV therapy, and (5) Virologic suppression.[5] Population-based studies have yielded sobering statistics about the degree to which HIV-positive individuals in the United States are engaged in care, among whom only 19-28% are estimated to have achieved virologic suppression.[5-7] Optimizing engagement in care at each stage of the continuum is a critical national priority, as engagement in care decreases individual morbidity and mortality, and dramatically reduces the risk of HIV transmission to others.[8]

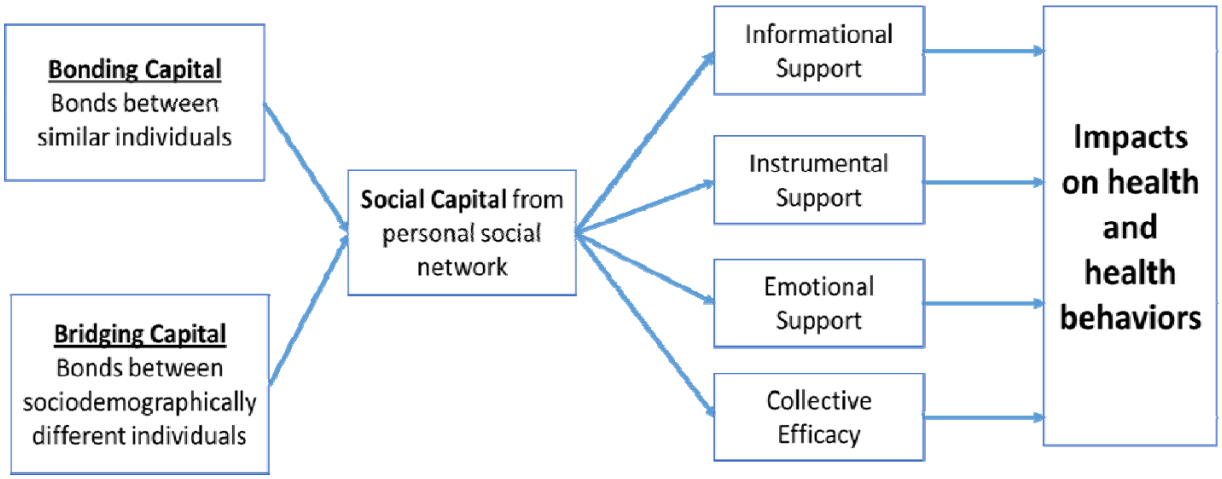
***1.2.4 YBMSM are at risk for suboptimal engagement at multiple stages along the continuum, including virologic suppression, adherence, and retention**:* Adolescents, including YBMSM, are less likely to achieve and maintain virologic suppression compared to the adult population.[9-12] Unpublished data from the Grady Infectious Disease Program clinic (IDP) showed that only 46% of adolescents aged 13-24 achieved viral suppression within a year of commencing ARV therapy,[13] compared to the 72% for adults in the same clinic building.[14] Virologic failure (VF) in the growing young patient population has enormous public health implications, including increased risk of HIV transmission, evolution and transmission of multi-drug resistant HIV strains,[15] and an increase in AIDS-related morbidity and mortality. Poor adherence to ARVs is the strongest predictor of VF in horizontally/behaviorally-infected adolescents.[12,16] Understanding and modifying factors that influence ARV adherence in this population is therefore of paramount importance. ARV adherence in HIV-infected adolescents is often sub-optimal, and there is a dearth of evidence-based interventions to address this problem. A multitude of factors are variably associated with adherence in adolescents, including contextual factors, developmental factors, co-morbidities, regimen factors and personal characteristics.[17-26] Socio-contextual factors are repeatedly cited as important influences on adherence, but they are rarely studied or incorporated into interventions, in spite of repeated calls for approaches to adherence support that place equal focus on network-level factors.[17,27,28] Even when youth are initially adherent, research also indicates that YBMSM may be difficult to retain in HIV care as youth and ethnic minorities face more challenges to accessing and staying in medical care in general.[29]

1.2.5 Social capital. We define social capital as *"the sum of an individual's resource-containing, reciprocal, and trustworthy social network connections."*[16] The **social network** is the core element of social capital.[30] Social capital is a multidimensional construct that includes structural, cognitive and functional features of social networks. Features such as the size and diversity of a person's network, as well as the socioeconomic and other resources owned by contacts in that network, all have a bearing on the quality and quantity of social capital that can be derived therein.[31,32]

Researchers have outlined several mechanisms through which social capital can affect health and behavior: through informational support, instrumental support, emotional support and collective efficacy (Figure 1).[16] That is, through one's social network connections (be it friends, family, workmates, casual acquaintances, etc.), an individual can obtain informational, instrumental and emotional support. Adequate network connections are needed to develop *collective efficacy, which refers to community action for self-empowerment*. A prior multi-site study in three sub-Saharan African nations highlighted social capital as a key mechanism underlying engagement in HIV care.[33] The researchers found that due to the structure of many of those societies, HIV-positive individuals were able to draw on network connections for emotional support, transportation to the clinic, and reminders to take medication—all of which positively impacted HIV clinical outcomes. In Dr. Hussen's own prior qualitative work in Ethiopia, similar patterns were found. Additionally, Hussen found that community participation enhanced HIV-positive individuals' personal sense of well-being and motivation to adhere to care.[34]

Importantly, scholars in the field have also highlighted different *types* of social capital.[35] Social capital can be further divided into *bonding capital*, which refers to trusting and cooperative relations between similar members of a network, and *bridging capital*, which consists of relations between people who differ in some sociodemographic sense (i.e. age, class, ethnicity, sexual identity). The majority of existing studies, however, have yet to differentiate between the effects of bonding and bridging capital on health.

Figure 1. Mechanisms of Social Capital Effects on Health



In the domestic setting, social capital has been found to be protective against a range of adverse health outcomes in adolescents and young adults, including obesity, smoking, and teen pregnancy. There is evidence that the protective effects of social capital on health may be particularly pronounced in the life trajectories of urban minority youth.[36,37] Social capital has not been studied among HIV-positive YBMSM to date. Factors such as poverty, lack of education, and racism shape individuals' networks and could restrict the accumulation of social capital for marginalized youth such as HIV-positive YBMSM.[36] At the same time, YBMSM often have strong informal support networks and robust community connections that may increase social capital and resiliency in the face of obstacles.[38,39] **YBMSM living with HIV therefore face many potential threats to their social capital,**[29,40] **but may benefit more from interventions to augment it.**

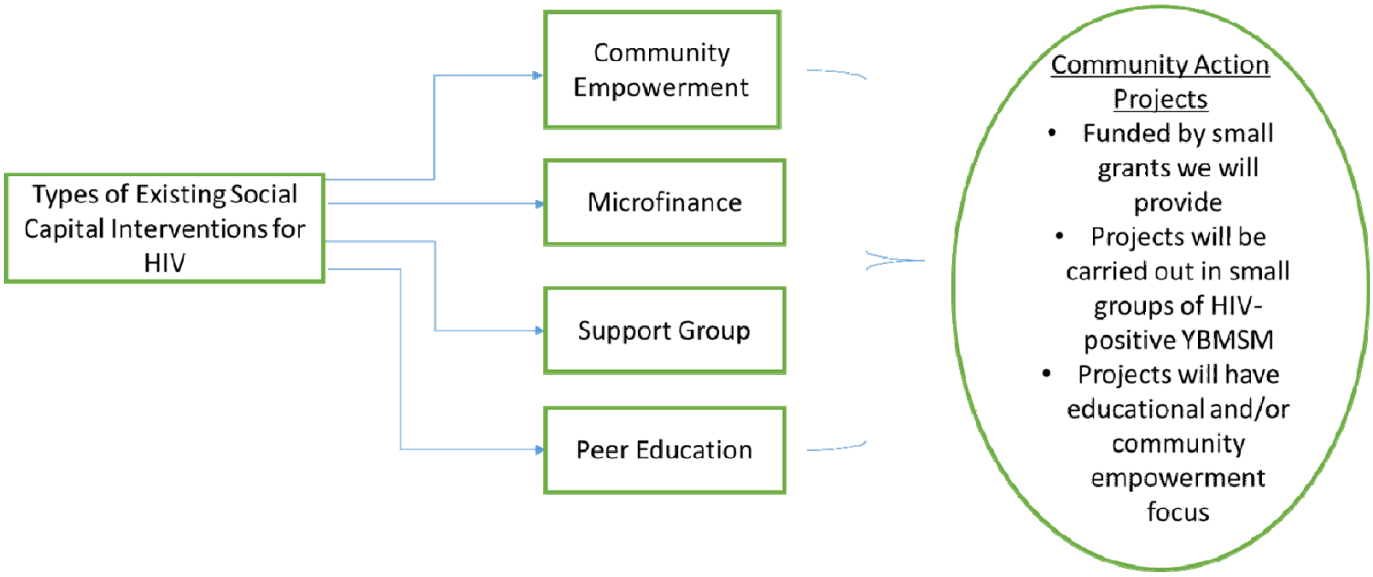
1.2.6 Social Capital Interventions. Interventions designed to build social capital as a way of improving HIV-related outcomes (including both prevention and treatment) have utilized four main strategies, all of which inform the novel social capital intervention that we propose to develop here. These existing interventions can be described as ***community empowerment interventions***, ***group-based microfinance interventions***, ***support group interventions***, and ***peer interventions*** focused on building social capital among group members.[41] ***Empowerment interventions*** have included programs focused on sex workers in India and Latin America, and have shown association with reduced sexual risk behaviors.[42,43] ***Group-based microfinance*** involves the awarding of a small grant to a group of individuals to facilitate public health message development for improved HIV care, which theoretically can lead to economic empowerment as well as bonds between group members.[44] The efficacy of group based microfinance interventions has primarily been shown when this strategy is combined with other interventions such as health education programming, and to date, these programs have primarily been implemented and tested in sub-Saharan Africa.[45] ***Support group interventions*** have been used worldwide and some of these aim to build social capital among group members as a way of improving psychological and clinical outcomes. Finally, ***peer interventions*** utilize members of high risk groups as leaders and educators.[46,47]

While the above strategies have been developed and tested in other settings, there is a dearth of social capital-based interventions with a focus on YBMSM in the United States. **We are therefore proposing to empower HIV-positive YBMSM to develop an intervention that will combine all of the above elements into a cohesive social capital intervention with and for HIV-positive YBMSM**. As detailed later in the protocol, we will provide guidance through a YCAB for YBMSM to develop and test a group-based intervention for HIV-positive YBMSM centered on a group ***community action project***. That is, each group of HIV-positive YBMSM will be given a micro-grant to develop programming that empowers participants and their communities, and also builds social capital within the group during the process (Figure 2).

1.3 Justification for Study: While our preliminary research indicates that social capital is likely to be important for engagement in HIV care among YBMSM, this area is understudied at the time. Additionally, there is a critical need for novel strategies to improve engagement in this population, which will have implications for both clinical and public health outcomes. We are planning an in-

depth exploration of social capital in this population that will inform a novel intervention designed to augment social capital among YBMSM.

Figure 2. Social Capital Interventions Informing Proposed Community Action Projects



1.4 Intended/potential use of study findings: We hope to apply our findings towards the creation and refinement of an intervention for YBMSM living with HIV that can be disseminated and implemented in other settings in the future.

1.5 Study Design/Location: The study design includes a cross-sectional mixed-methods study for the formative research, followed by a randomized controlled trial to pilot and test the intervention, as depicted in Figure 3. All study activities will take place in Atlanta, Georgia.

1.5.1 Aims and Hypothesis

Aim 1: To characterize the social networks of YBMSM living with HIV with respect to the multiple dimensions of social capital using a mixed-methods research design.

Aim 2: To develop a social capital-based intervention to enhance engagement in care among HIV-positive YBMSM utilizing a participatory, youth-centered approach.

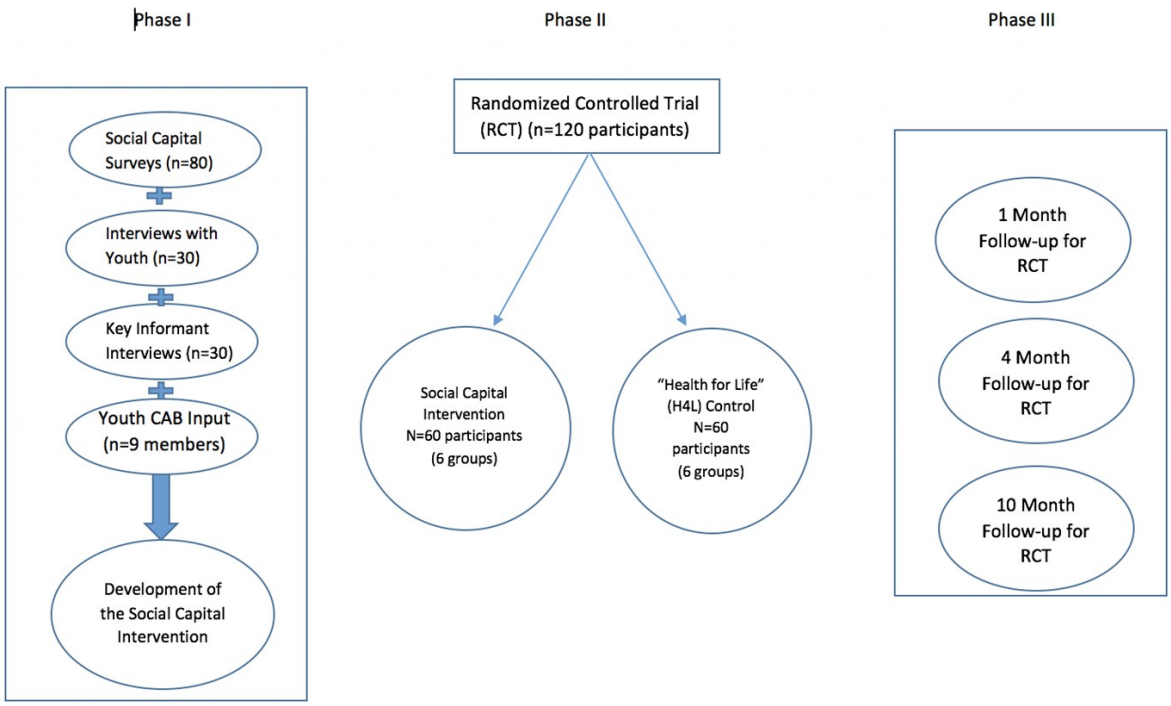
Aim 3: Implement a randomized controlled trial with groups of HIV-positive YBMSM to develop and pilot our social capital interventions.

Aim 3a: To assess participant satisfaction and feasibility of the intervention.

Aim 3b: To test impact on social capital and HIV care engagement outcomes.

2.0 PROCEDURES/METHODS: Design

Figure 3. Study Design*



***We envision each arm in Phase II will have six groups of approximately 10 participants, completing the same intervention or H4L curriculum.**

As depicted in Figure 3 above, there are three phases of our research, each corresponding to one of the study aims: **Phase I: a mixed methods exploration of social capital and development of a social capital intervention; Phase II: a randomized controlled trial of the social capital intervention; and Phase III: 1-, 4-, and 10-month follow up for the RCT.** For Phase I, we will recruit 30 HIV-positive YBMSM and explore the nature of their social capital and social networks using in-depth individual qualitative interviews (IDIs). We will also analyze previously collected survey data (from a pilot study of 80 YBMSM, conducted last year) to quantitatively understand relationships between social capital constructs and engagement in care. We will also engage 30 key informants (healthcare providers and community-based organization (CBO) staff) in IDIs to gain their input about how best to augment social capital among YBMSM. We will use the information collected in the formative research, and together with a Youth Community Advisory Board (YCAB), we will develop an intervention to augment social capital among YBMSM. In Phase II, we will conduct an RCT with 120 YBMSM, split between 6 intervention groups and 6 control groups. Groups in each arm will implement the same intervention (social capital intervention arm) or receive the same health education information (H4L). Justification for the number of groups is provided below. Finally, in Phase III, we will obtain follow-up data at 3 and 9 months after study completion.

2.1 **Procedure: Phase I (Aim 1-Background work on social capital in YBMSM)**

Part 1a: In-depth Interviews with YBMSM (n=30)

Procedures-Interviews with YBMSM: All interviews will take place in a private and quiet room within the IDP clinic, the Rollins School of Public Health, or an alternate location that is mutually convenient. Interviews will be conducted by a graduate research assistant who is trained in qualitative methods and interviewing techniques. All interviews will be digitally recorded for subsequent professional transcription. Written informed consent will be obtained before beginning the interview. Interviews will be expected to last approximately 60-90 minutes each.

Interview guide: We have developed a semi-structured interview guide based on the theoretical conceptualizations of social capital and resilience presented above (Appendix C). That is, we will ask questions to elicit participants' experiences with the various dimensions of social capital including bonding capital, bridging capital, and collective efficacy. We will elicit participants' perspectives on the types of support that they do or do not receive, and the sources of support in their lives—examples may include biological family, LGBT organizations, and church communities. We will also ask for examples of community involvement. Finally, we will ask for participants' recommendations regarding potential strategies for improving social capital in their lives.

Sample Size: We plan to interview 30 YBMSM in this portion of the study. Based on our prior experiences with qualitative research, we expect this to be a sufficient sample size to achieve thematic saturation.

Qualitative Data Analysis: All interviews will be digitally recorded and transcribed verbatim by a professional business transcription service. Qualitative data will be de-identified during this transcription process. Transcripts will then be uploaded into the MaxQDa qualitative data management software (VERBI Software, Berlin, Germany) for further processing and analysis. We will conduct thematic analysis using a combination of inductive and deductive coding. In *deductive coding*, we will apply pre-determined codes from our theoretical model (*e.g.* collective efficacy) to segments of text that correspond to each theme. In *inductive coding*, we will elicit themes that emerge from the text but were not previously considered (for example, *church community* could come up as a recurring theme among several participants and be added to our code lists). Once the list of themes has been created, we will create a codebook listing the codes and strict definitions to delineate which passages should be labeled with a certain code. Two members of the study team will each code 5 transcripts in parallel to determine inter-coder reliability. If any significant disagreements arise in coding, the entire research team will discuss each discrepancy and come to a consensus in order to finalize the codebook. Two graduate research assistants (GRAs) will then split and code the remainder of the transcripts. This coding will facilitate further analysis of the transcripts by comparing cases and summarizing comments under each code across participants.

Tokens of Appreciation: We will provide participants with two gift cards (value $75) as a token of appreciation for their time and will also provide Metropolitan Atlanta Rapid Transit Authority passes (MARTA cards; $5 fare for a single round-trip) if needed for transportation assistance. $25 will be given on the first day and $50 will be given on the second day.

Timeline and feasibility: Given our prior success in recruiting HIV-positive YBMSM for qualitative interview studies, we expect to be able to complete these interviews within the first 6 months following project determination and we expect to complete qualitative analysis within months 6-12.

Part 1b: Additional In-depth interviews with YBMSM (n=30)

In order to understand additional life experiences, desires, and intentions of YBMSM living with HIV, specifically surrounding forming families and parenting, in-depth interviews separate from the ones described in part 1a will be conducted as a sub-study.

Procedures – Additional In-depth interviews with YBMSM: Participants for these interviews will be recruited from the database of those who have completed the screener form for the larger study and indicated that they would like to be contacted for other studies, or from those participants that have already participated in the intervention or control arms. Interviews will take place in a private and quiet area in the IDP clinic, at the Rollins School of Public Health, or in an alternative location that is convenient for both the participant and interviewer. These interviews will also be conducted by a graduate research assistant who is trained in qualitative methods and interviewing techniques. All interviews will be digitally recorded and subsequently transcribed by a graduate research assistant trained in transcription. Verbal informed consent will be obtained prior to the interview. Interviews may last approximately 45-60 minutes each.

Interview guide: We have developed a semi-structured interview guide based on informal discussions Dr. Hussen has had with prior patients, as well as discussions had with healthcare providers specializing in fertility options and childbearing options for individuals living with HIV. Various themes that are a part of the larger study, including identity and community, are also incorporated into this interview guide in order to understand the intersections of HIV status, black and gay identities, communities, engagement in care, and the desire to form families and become a parent.

Sample size: Similar to the in-depth interviews described in part 1a, we plan to conduct 30 interviews for this portion of the study, with the expectation that this result in sufficient data to reach thematic saturation.

Qualitative data analysis: The data analysis process for these interviews will be similar to the process that will be conducted for the interviews described in part 1a. All interviews will be digitally recorded and transcribed verbatim by a graduate student assistant trained in transcription. During transcription, the interviews will be de-identified and subsequently uploaded into MaxQDa qualitative data management software. Inductive reasoning will be used to develop a list of themes that are representative of the themes that arise in the interviews as the transcripts are reviewed. After the creation of a list of themes, we will create a codebook containing codes that reflect the themes and are defined clearly, so that these codes can be used to label passages of interview transcripts. Similar to the process of coding the in-depth interviews described in part 1a, two members of the study team will each code 5 transcripts in parallel to determine inter-coder reliability. In the event of disagreements, the research team will discuss the discrepancies to arrive at a consensus for the finalized codebook. One graduate research assistant will then code the remaining transcripts. Transcripts will be further analyzed through comparison.

Tokens of appreciation: Participants will be provided with a $25 gift card as a token of appreciation for their time. Metropolitan Atlanta Rapid Transit Authority passes (MARTA cards; $5 fare for a single round-trip) will also be provided if needed for transportation assistance.

Timeline and feasibility: Interviews are expected to be completed within the first 4 months from the start of the sub-study (approximately September 2019), given our prior success in recruiting HIV-positive YBMSM. Analysis is expected to be completed approximately 4 months following data collection.

Part 1c: Quantitative analysis of previously collected social capital and engagement data (n=80)

In order to understand which components of social capital are most important for YBMSM and engagement in care, we will draw on quantitative data that is currently being collected with YBMSM in our clinic. Dr. Hussen successfully competed for a developmental grant from the Emory Center for AIDS Research (CFAR), in which she is beginning to explore social capital among YBMSM at the IDP clinic. The study has a cross-sectional design and participants' involvement involves a single study visit in which they complete an ACASI including our modified social capital scale (MSCS). We also obtained the participants' permission and abstracted data for each patient with respect to appointment adherence, and viral suppression. We can therefore measure associations between engagement outcomes and various dimensions of our social capital measure.

Measure: There is no existing published scale for social capital which has been validated in a United States youth population or in YBMSM more specifically. However, as mentioned above, we have recently modified, pilot tested, and validated Chen's Social Capital Scale to create the MSCS) that we will use in this study. Although Chen's original scale addressed conceptual domains of interest (bonding social capital, bridging social capital, and collective efficacy), it was developed for use among adults in China and therefore contained items that we not culturally relevant to YBMSM. Our MSCS had excellent reliability in an online sample of YBMSM (α=0.88; data not yet published). The scale contains subscales for bonding and bridging capital, and it also contains items that specify sources (including family, friends, and LGBT organizations) and types of support (e.g. emotional support, instrumental support and informational support). We can therefore determine which components of individuals' networks are most related to care engagement outcomes using our cross-sectional data.

Sample Size: 80 HIV-positive YBMSM in care at the Grady IDP clinic

Data Analysis: An odds ratio plus the 95% confidence interval will be calculated to measure the degree of association between retention in care measures and total social capital (all analyses will also be computed for bonding/bridging subscales alone, as well as for item clusters focusing on different dimensions of social capital). Odds ratios will also be calculated to measure the degree of association between other risk factors (education, employment, age, depression, substance use, HIV stigma and CD4 cell count) and patient retention. Additionally, total social capital will be compared between engaged and non-engaged patients using a two-sided two-sample t-test. Other potential risk factors will be compared between retained and non-retained patients using a chi-square test or Fisher's exact test for categorical covariates and a two-sided two sample t-test for continuous covariates.

Multivariable analyses: Covariates significant to at least $P \leq 0.20$ in the univariable analyses will be used in multivariable logistic regression analyses. Although empirical techniques will be used to identify important covariates, theoretical expectations from our social capital conceptual framework will also augment these decisions. Interactions between covariates will be evaluated, either because suspicions are raised by clinical judgment before the analyses are performed or by statistical examination. Forward stepwise selection will be used if necessary to choose prognostic variables for a multivariable logistic regression model. The odds ratio and its 95%confidence interval will be calculated for each risk factor in the presence of others in the final model.

Timeline and feasibility: Given that this data will already be collected, when the MARI award period begins, and utilizing the statistical support that we have included in our budget, we expect to be able to complete this statistical analysis within the first 6 months of the project period.

Part 1d: Key Informant Interviews

To answer this question, we will conduct IDIs with up to 30 key informants who have experience and interest in working with YBMSM living with HIV. Key informants may include healthcare workers (HCWs) and representatives of community-based organizations (CBOs) who work with YBMSM.

Procedures-Interviews with Key Informants: Procedures will be similar to the YBMSM interviews described above, except that interviews may take place at a key informant's place of work (*e.g.* a CBO) or a mutually agreed upon location in the community. As the interview is likely less sensitive in nature for a key informants talking about their work as opposed to YBMSM reporting on their own lives, interviews with key informants can be more flexible in terms of public locations.

Interview guide: We have developed a semi-structured interview guide to focus instead on the key informants' work experiences with YBMSM and their observations of social capital in this population (Appendix D). We will still address the various theoretical dimensions of social capital including bonding capital, bridging capital, and collective efficacy as well as detailing types of support that key informants feel are present or missing among their clients (informational support, instrumental support, emotional support). We will ask for key informants' recommendations regarding potential strategies for improving social capital in the lives of YBMSM.

Sample Size: We plan to interview up to n=30 key informants. Based on our prior experiences with qualitative work, we expect this to be a sufficient sample size to achieve thematic saturation.

Qualitative Data Analysis: As described in 1a: In-depth interviews with YBMSM..

Timeline and feasibility: This analysis will overlap with the qualitative analysis of YBMSM interviews described above. Given our established network of community contacts and familiarity with clinical providers, we expect to be able to complete these interviews within the first 6 months of the award period, and to complete qualitative analysis within months 6-12.

2.2 Procedure**: Phase II (Aim 2- Intervention Development)**

Creation of the Youth Community Advisory Board* (YCAB) (N=9)*: Interventions that include stakeholders (in this case, YBMSM) in their development have the potential for increasing feasibility, acceptability and sustainability. Our YCAB will be made up of HIV-positive (by self-report) YBMSM who are willing to serve in an advisory capacity over the course of the project. We will form the YCAB, with nine individuals, within the first year of the Minority HIV/AIDS Research Initiative (MARI) award period to inform all subsequent phases of the research. We will aim to recruit a YCAB that is diverse in terms of socioeconomic status, educational attainment, and extracurricular interests. *Of note, given their intricate involvement in intervention development, members of the YCAB will be excluded from participation in the randomized control trial (Phase II).*

Time Commitment: Once membership is solidified, the YCAB will meet approximately every two weeks throughout the award period. We expect meetings to last between 2-3 hours on average, and they will be scheduled at mutually convenient times for the participants. YCAB members will be hired as temporary employees at Emory University and will be compensated for their time at a rate of $12.50/hr.

Development of Social Capital Intervention: The development of our social capital-based intervention guidelines will require integrating scientific literature, preliminary data (both

qualitative and quantitative), and the perspectives of YBMSM, members of the YCAB, and other community and clinic-based stakeholders.

The development of the social capital intervention will continue throughout the first 18 months of the award period. Intervention development will be a continuous and iterative process during this timeframe and will involve Dr. Hussen, her mentors and collaborators, the study team and the YCAB. We will present qualitative and quantitative data from Phase I formative research to the YCAB as it is collected and analyzed as a way of "member checking" our results. We will also solicit ideas for the social capital intervention, discussing ideas in an iterative process until we have completed development of the intervention. Finally, we will have the YCAB test out a mock intervention with our team, and give us feedback on what works or does not work well in our curriculum. We will present the intervention to the YCAB as many times as needed in an iterative fashion until the study team and YCAB are satisfied with the final product. Our YCAB will give us input on every aspect of the intervention, including timing, location, content, and process Before we are ready to share the intervention as part of our RCT, we will standardize the intervention in a standard operating manual which will also be reviewed by the YCAB.

The social capital intervention will be a group-level, multi-session program that entails a structured curriculum and process culminating in a community photovoice project. ***The specifics of the community photovoice project are yet to be determined, and will be decided on with the YCAB as a part of the formative work.*** The curriculum will also include components focused on training in advocacy, HIV knowledge, and project planning.

2.3 Procedure: Phase II and III (Aim 3- Randomized Controlled Trial) (n=120)

***Randomized Controlled Trial Overview*:** We propose a prospective RCT in which groups of YBMSM will implement a novel intervention with the goal of enhancing social capital and engagement in care among YBMSM living with HIV. Sixty of our participants will be randomized to the treatment arm (divided into at least 6 groups) and participate in the social capital intervention, while the other 60 will be randomized to a group-based health promotion intervention (divided into at least 6 groups) that does not explicitly aim to build social capital (Health for life, or "H4L"). (See Figure 3) Each of the 6 groups in the treatment arm will implement the same intervention. Six groups are necessary in order to ensure that each group has no more than 10 individuals, ensuring that groups are neither too small nor too big. Each of the 6 groups in the group-based health promotion intervention arm will also complete the same curriculum. We will measure social capital using our Modified Social Capital Scale (MSCS; Appendix F, Section 2) at baseline, immediately after completing the intervention (approximately 1 month) and at 4 and 10 months after beginning the intervention. We will also abstract clinical data from electronic medical records at these time points in order to quantify any effect on our care engagement outcomes.

***Overview--Intervention Arm**:* The social capital intervention will be implemented according to the detailed guidelines and manual developed in Phase I above. We will plan for our intervention (and our control condition) to be delivered in either a one day or consecutive two day group meeting at Emory University Rollins School of Public Health or another agreed upon location, at mutually convenient times for the participants. Staff members will be flexible in case evening or weekend meeting times are more convenient for the study participants. The exact number of sessions and

format of the intervention may be modified based on YCAB input; it may be that the intervention can be delivered in fewer sessions, or in a retreat format, to enhance acceptability and retention.

Community Photovoice Project: Our social capital intervention will focus on developing skills and group-work that culminate in participant-derived ***photovoice projects.*** This is based on our own and others' prior qualitative work that demonstrates HIV-positive YBMSM's interest in HIV education, peer mentoring, and community involvement.[48,49] We envision having six sets of intervention and control groups with 10 YBMSM in each group (Figure 3). *Each group of YBMSM will be encouraged to complete a 30 day photovoice challenge.* The 30 day challenge is based on a prior community action project done as a part of our CFAR-funded research, which was a Photovoice project conducted by Dr. Hussen and an MPH student.[50] Photovoice is a participatory action research methodology in which groups of individuals from a population of interest are given cameras to document events, people and places of significance in their lives.[51] In that project, n=7 YBMSM were recruited from AID Atlanta (one of our CBO partners) and given digital cameras with which to document and describe events, people and places of significance in their lives. Their pictures and the ensuing discussions gave us insight into community and identity within the population. Costs included digital cameras, compensation for transportation to meetings, and printing of photos for display in a booklet and a community exhibit.

As we saw preliminarily with our Photovoice experience, we expect that the process of working together with other YBMSM and engaging the community will enhance the social capital of individuals in the intervention arm by creating bonds that will lead to the aforementioned health-promoting mechanisms: informational support, emotional support, instrumental support and collective efficacy (Figure 2).

Again, the exact nature of the 30 day challenge and the intervention will be determined in conjunction with the YCAB over the course of Phase I intervention development. (The control groups will not participate in the 30 day challenge). The process of working on the 30 day challenge as part of the proposed social capital intervention has the potential to increase bonding social capital through the group's interactions with one another, as well as bridging social capital through meaningful connections with community partners and study staff. Finally, the act of creating and executing a community-oriented project will also increase participants' sense of collective efficacy (as measured by items in the MSCS), another important component of social capital.

Overview--Control arm: The control arm will participate in a health education intervention that will be delivered in a group, but without a specific goal of creating group cohesion or social capital. The intervention will be a modified version of "Health for Life" or H4L, which was used as a control arm intervention in a recently completed protocol of the Adolescent Trials Network which was co-chaired by Dr. Harper (University of Michigan). This intervention was specifically developed for young MSM of color and focuses on general health topics including diet, exercise, and safe sex. Details about the Health for Life program are included as Appendix G. We will modify the H4L intervention as needed based on the input of our YCAB. Similar to the intervention arm, the control participants will participate in either a one day or a consecutive two day group meeting at a convenient time and location. The exact number of sessions and format of

the intervention may be modified based in YCAB input; as with the intervention arm--it may be that the intervention can be delivered in fewer sessions, or in a retreat format, to enhance acceptability and retention. The same format and number of sessions will be used for both the intervention and control arms.

Procedures for intervention and control participants:

Tokens of appreciation: We will provide participants with two gift cards (value $75) as a token of appreciation for their time and will also provide Metropolitan Atlanta Rapid Transit Authority passes (MARTA cards; $5 fare for a single round-trip) if needed for transportation assistance. $25 will be given on the first day and $50 will be given on the second day

Retention Plan: Our previous experiences have demonstrated the need to pay careful attention to participant retention: part of the role of the study staff is to remind participants about intervention sessions and study visits, scheduling, and discussing any issues they face in the trial procedures. In Dr. Camacho-Gonzalez's ongoing work with the Metropolitan Atlanta Community Adolescent Rapid Testing Initiative (MACARTI) trial, these procedures have resulted in at least an 87% retention among participants who were primarily HIV-positive YBMSM (and may be higher as the follow-up period has not yet ended).

Clinical Outcome Measures: Viral load values and appointment attendance will be extracted from the participants' electronic medical records (EMR). The goal is to abstract measures that correspond to the 0 month (baseline)and 10 month (long term follow-up) time points at which participants will be completing surveys. However, we recognize that lab tests (CD4, VL) in the clinical setting may not necessarily be conducted at a time that corresponds to the survey time point. In light of this limitation, and to make the procedures more uniform, we plan the following: (1) the baseline viral load will be the most recent measurement preceding study participation. If this is >6 months prior to the date of enrollment, this will be considered a missing value. (2) The 10 month viral load will be the first value drawn on or after the date that is exactly one year from the beginning of study participation. If this test is done >6 months after the target date, it will be treated as a missing value.

Study visits: In addition to attending the intervention sessions, participants in both arms will be asked to come to the IDP clinic or Rollins School of Public Health to participate in three study visits: One at baseline before starting the intervention (0 months), immediately after completing the intervention (around 1 month), 4 months and a long term follow-up at 10 months after study completion. The main purpose of these visits will be to complete a survey to measure any change in social capital between the pre- and post-intervention periods. The survey (Appendix F) will also include measures of other theoretically relevant constructs including depressive symptomatology, stigma, and social support. We will also verify the participants' most recent medical care facility and obtain medical record release forms to facilitate abstraction of data on engagement outcomes. Participants will receive tokens of appreciation for each completed study visit ($25 for the first visit and $50 for the second) and given MARTA cards at these visits.

Follow-up qualitative interviews: We will conduct n=30 qualitative in-depth interviews in Year 4 with a subset of interested participants who were enrolled in the social capital intervention arm, in order to understand their experiences in the program and solicit feedback for future implementation of the intervention. Procedures and analytic plans will be as described in the Phase 1 interviews above. Participants will sign a separate informed consent to participate, and will receive an additional $25 token of appreciation for their time if they choose to do so. The maximum total amount for tokens of appreciation for participants who do all sessions is $175.

2.4 Audience and stakeholder participation: Our study follows a community-based participatory approach designed to ensure stakeholder participation. First, we will conduct interviews with community stakeholders to inform our understanding of social capital in our target population. Second, we will create a youth community advisory board (YCAB) designed specifically to engage members of the community at each step of the process. Finally, at the end of the project, we will plan to disseminate findings not only in academic publications but also in a community forum.

2.5 Description of risks (physical, social, psychological, economic, other) to individual or group: Risks to participants from a physical standpoint are minimal, as there are no medical procedures being conducted in this study. There are risks from a social and/or psychological standpoint, primarily related to the potential for a breach of privacy which could lead to inadvertent disclosure of HIV status or sexuality. One source of such a breach could be study records; we will take the necessary precautions to prevent this including password protection of all participant records and de-identification of datasets before analysis. A second source of such a breach is other participants, as the activities include involvement in a group project with other HIV-positive individuals. We will make sure to explicitly discuss privacy concerns and instruct participants not to disclose others' participation and/or HIV status; however this will be impossible for us to enforce. We will ensure that participants are aware of this potential risk in the informed consent process.

2.6 Description of anticipated benefits to the research participant: If our intervention is effective, it will provide direct benefits to the participants in terms of improved social support, social capital and HIV related outcomes. Those in the control arm should also receive the benefits of a health education intervention that will improve their knowledge about HIV and other health issues.

2.7 Emergency care: Given the non-invasive nature of this study, it is not expected that involvement in either the control or treatment arm would lead to any physical or psychiatric emergencies. However, were an emergency to occur during the course of involvement, study staff would be instructed to contact the PI immediately via cell phone or pager. Dr. Hussen would then direct the participant to either the ER (including Grady Psychiatric Emergency Services if applicable) or their primary medical provider, and she would also record the adverse event for immediate reporting to the Emory IRB (Adverse Event form in Appendix H).

2.8 Study time line:

Activity	Pre-Award	Year 1				Year 2				Year 3				Year 4			
Research Activities																	
Team consolidation, hiring new staff, planning																	
Development of project guidelines/SOPs																	
IRB review: Emory, Grady																	
IRB review/project determination review: CDC																	
Qualitative interview guide development																	

Aim 1: IDIs with YBMSM																
Aim 1: IDIs with CBOs, providers																
Aim 1: Qualitative analysis																
Aim 1: Statistical analysis of survey data																
Aim 2: YCAB formation																
Aim 2: Intervention development																
Aim 3: Enrollment and follow-up of control arm																
Aim 3: Enrollment and follow-up of intervention arm																
Aim 3: Data analysis from pilot intervention/follow up																
New R01 application																

3.1 STUDY POPULATION

3.2 Description and source of study populaton and catchment area: We will recruit HIV-positive YBMSM from clinical, research and community settings. Flyers will be posted for self referral in the Grady IDP clinic, community-based organizations, and other venues (e.g. coffee shops) as directed by our YCAB (Example in Appendix H: final version will be created with YCAB input). Additionally, participants may be referred from other studies. Participants will be residents of the greater Atlanta area—with no strict boundaries provided they are able to get back and forth from their homes to the intervention sites in Midtown Atlanta.

3.3 Inclusion and Exclusion criteria:

3.2.1 Inclusion Criteria (participants):

- Age ≤ 29 years and ≥ 18 years
- Self-identify as Black/African-American (inclusive of multiracial identities)
- Male sex at birth
- Endorse history of sex with men ever (inclusive of gay and bisexual men)
- HIV-positive (self-reported by participant and confirmed by medical record)
- Able and willing to provide written consent and participate in surveys, interviews, and/or group intervention

3.2.2 Inclusion Criteria (key informants):

- Experience working with YBMSM in clinical or CBO settings
- Able and willing to provide verbal consent and participate in in-depth interviews

3.2.3 Exclusion Criteria

- Age < 18 years or ≥ 30 years
- Unwilling or unable to provide written informed consent
- Enrollment in one phase of the study is an exclusion criteria for enrollment in other phases

3.3 Justification for inclusion/exclusion criteria: We are focusing exclusively on YBMSM in this study due to the disproportionate impact of HIV in this population, as detailed in the literature review above. We are aiming to develop an intervention that is culturally and developmentally appropriate, and as such are limiting our enrollment to this target population.

3.4 Estimated number of participants: We plan to enroll 180 total participants (120 in the randomized controlled trial and 60 in preliminary interviews.

3.5 Sampling, including sample size and statistical power:

Based on our MSCS scale characteristics in our previous online survey study (mean 26.6, standard deviation 7.0), we can estimate that a sample size of n=106 (n=53 in each of the intervention and control groups) would allow us to detect approximately a 15% increase in social capital attributable to our intervention (using 80% statistical power). For the RCT, we will therefore aim to recruit n=120 patients (accounting for some attrition): based on our team's previous work in the same geographic area, we believe this to be a feasible number of YBMSM to recruit during the specified time period from our IDP clinic and community partners.

Table 1. Power calculation

Control Patients	Intervention Patients	Control SC Mean	Intervention SC Mean	Detectable Effect Size	Detectable Percent Increase in SC
31	31	26.6	31.9	0.75	20%
39	39	26.6	31.3	0.67	17.5%
50	50	26.6	30.7	0.58	15.4%
53	53	26.6	30.6	0.57	15%
77	77	26.6	29.9	0.47	12.5%
114	114	26.6	29.3	0.38	10%

3.6 Enrollment

Phase I IDIs with YBMSM: We will recruit young men from the IDP clinic as well as from our CBO partners AID Atlanta, NAESM and Positive Impact. Recruitment will also include self-referral from email and social media announcements as well as posted flyers at community locations and within the clinic. Flyers and announcements will contain a link to an online screening survey as well as a telephone number to contact study staff. Interested individuals will be screened for eligibility criteria via phone or online survey (must be HIV-positive, biologically male, endorse sexual contact with men, and between the ages of 18 and 29). If eligible, study staff will then contact the participant to schedule an interview.

Phase I IDIs with Key Informants: We will directly contact clinic providers and CBO employees who we already know to be involved in work with YBMSM and offer participation in our study. We will also ask YBMSM in the initial qualitative interviews to nominate individuals from the community who they think could provide useful information. Finally, we will send email announcements to all of the IDP clinic and staff as well as listservs of the CBO partners, so that any additional interested individuals can self-refer into the study.

Phase II YCAB formation: Recruitment: Although YCAB members are not research participants, they will also be recruited as a part of the study. We will recruit YCAB members from a wide range of sources with the goal of retaining a diverse group of committed youth to advise us on our intervention development. Sources will include CBOs, our clinic site, and email advertisements to community listservs. As mentioned earlier, we will also specifically ask for recommendations from our key informants in the CBOs and healthcare settings. Eligible youth will be YBMSM ages 18-29 who are living with HIV, and we will attempt to have representation throughout this age range. We will choose 9 members for the YCAB based on diversity of age, experience, education, and

general interests. At the latest, we hope to complete this process by month 6 of the award period.

Phase III Randomized Controlled Trial: Recruitment: We will recruit YBMSM from the IDP clinic as well as from our CBO partners AID Atlanta, NAESM and Positive Impact. Community recruitment will occur via self-referral from email and social media announcements as well as posted flyers at community locations and within the clinic. When interested individuals contact the study team, they will be screened for eligibility criteria via phone or online survey. Of note, participants do *not* need to be patients at the IDP clinic; as long as they consent to release of medical records and chart abstraction by our study team, we will be able to obtain HIV related outcome data. If eligible, study staff will then contact the participant to schedule an interview. We will also directly contact and offer screening to patients in our clinic who meet the age criteria (aged 18-29), as long as the medical providers agree to the patients being directly approached at that time. The eligibility screening can be done in person, via phone or via an online survey. At other times, we will also pass out flyers and other promotional materials at events that may be likely to be frequented by YBMSM (e.g., Gay Pride festival), and we will consult with our YCAB for advice about such venues and events. We will also do on-site recruitment at the clinic and community venues/events, in which we will approach potential participants and ask if they are interested in completing an online screening survey for eligibility in our study. If yes, they will have the option to complete the survey on a tablet at that time. We will also use the snowball sampling method to recruit participants. After completing the intervention, we will distribute 5 flyers to each participant to distribute to people within their social networks as referrals to our program. These flyers will be marked with a number that is unique to each participant. If a potential participant contacts us through the referral method, they will provide the number marked on the flyer. These potential participants will then complete an online screening survey for eligibility in our study.

3.7 Consent Process: In order to screen potential participants for eligibility for the RCT, we will obtain online consent – this will be accompanied by a verbal consent discussion of the consent document if a staff member is present (e.g., at a community event or in the clinic), and will be online only if a participant is self-referring to the eligibility survey from a flyer or friend. For the RCT participants, we will obtain written consent. The consent form is attached and includes specific permission to access participants' medical records for the purposes of abstracting the clinical outcomes (Appendix B). We are requesting a waiver of written consent for the IDI participants (YBMSM as well as key informants) as their signing of the consent form would be the only written record of participation and therefore could increase potential for breach of confidentiality. There is precedent for such waivers in our prior research; furthermore, federal regulations state that the IRB may waive the requirement for written consent if this will be the only record linking the subject and the research, and the principal risk would be potential harm resulting from a breach of confidentiality (45 CFR 46.117(c)). We will obtain verbal consent using the scripts attached to this application (Appendix A). YCAB members will not consent as they are not technically research participants, but rather advisors to the research process.

3.8 Tokens of Appreciation:
In Phase I, participants (whether YBMSM or key informants) will receive $50 cash or gift card for participating in in-depth interviews. Participants in the RCT will receive $25 cash/gift card for the first intervention session and $50 for the second intervention session. Also, they will receive $25 for taking the social capital surveys at 4 months and 10 months after study completion ($150 total). The subset who participate in post hoc qualitative interviews will receive an additional $25 for that visit and therefore receive a total of $175 over the course of 10 months participating in the study. Participants who refer up to 5 potential participants to the study will receive $10 for each participant that enrolls in the study (Up to $30). Additionally, MARTA cards (valued at $5/round-trip) will be offered to all participants in all phases to enable them to get to the study sites and participate.

4.1 VARIABLES/INTERVENTION

4.2 Variables

Table 2: Variables and Measures

	Method of Measurement	**Number of items**	**Timeline**
Social Capital (Primary Outcome)	Modified Social Capital Scale (based on Chen, et al.)[16]	10	Phase I: Analysis of previously collected data Phase III: RCT participants at 0, 1, 4 and 10 months

	Qualitative Interviews	n/a	Phase I: In-depth interviews with YBMSM living with HIV Phase III: Pre- and post-intervention interviews
Engagement in HIV Care (Secondary Outcomes)			
Viral load suppression	Electronic medical record abstraction	n/a	Phase III: RCT participants at baseline, post-intervention and 10 months (if available; see page 17 for more detail)
Retention in Care	Electronic medical record abstraction	n/a	Phase III: RCT participants at 0 and 10 months
Antiretroviral adherence	Single item self-report [52]	1	Phase III: RCT participants at 0 and 10 months
Correlates (measuring other factors shown to relate to engagement in care among YBMSM in prior work)			
CD4 count (recent and nadir)	Electronic medical record abstraction	n/a	Phase III: RCT participants at baseline and post-intervention 10 months (if available; see page 17 for more detail)
Demographics	Survey questions	23	Phase III: RCT participants at 0, 1, 4 and 10 months
Depression	CES-D[53]	20	Phase III: RCT participants at 0, 1, 4 and 10 months
HIV Stigma	HIV Stigma Scale[54]	10	Phase III: RCT participants at 0, 1, 4 and 10 months
Ethnic Identity	Multi-Ethnic Identity Measure[55]	12	Phase III: RCT participants at 0, 1, 4 and 10 months

Gay Identity	Internalized Homonegativity Inventory[56]	23	Phase III: RCT participants at 0, 1, 4 and 10 months
Drug Abuse	CAGE-AID[57]	4	Phase III: RCT participants at 0, 1, 4 and 10 months
Social Support	Zimet's Multidimensional Social Support Scale[58]	12	Phase III: RCT participants at 0, 4 and 10 months
Group Dynamics	Selected items from Schulz, Israel and Lantz[59]	20	Phase III: RCT participants at 0, 1, 4 and 10 months
Social Networks	Lubben Social Network Scale	6	Phase III: RCT participants at 0, 4 and 10 months
Engagement with Health Care Provider	HCP Scale	13	Phase III: RCT participants at 0, 4 and 10 months
Identification and Involvement With the Gay Community	Identification and Involvement With the Gay Community Scale	8	Phase III: RCT participants at 0, 1, 4 and 10 months
General Wellbeing	The General Well-Being Schedule (GWB)	18	Phase III: RCT participants at 0, 1, 4 and 10 months
Psychological Distress	Brief Symptom Inventory	53	Phase III: RCT participants at 0, 4 and 10 months

Outcome Measures: The **primary outcome measure will be social capital**. The core measure of social capital that we will use is our Modified Social Capital Scale (MSCS) described above, which we developed and validated exclusively with YBMSM. Our aim is to discover whether social capital improves as a result of being in the social capital intervention, and also to see if there is any similar effect in the control arm. **Secondary outcomes will be measures of HIV care engagement**, namely: (1) Retention in care, (2) Adherence to medications, and (3) HIV viral load suppression. As per Institute of Medicine (IOM) recommendations, ***retention in care*** will be measured by determining, within the 10 months of the study period, (a) participation in continuous care, that is, at least two or more routine HIV visits at least three months apart, (b) receiving two or more CD4 tests, and (c) receiving two or more viral load tests.[60] ***Adherence to antiretroviral medications*** will be measured using a composite of single item self-report question and pharmacy refill records. ***HIV viral suppression*** will be considered achieved if the medical records report a viral load below the level of detection for the site-specific assay. Viral load values and appointment attendance will be extracted from the participants' EMR.

4.3 Intervention Content: As the details of the intervention will be influenced greatly by the formative research and the input of the YCAB, it cannot be described in full detail at this time. The main intervention delivery will consist of either a one day or a consecutive two day group

meeting among the YBMSM with time divided between health education and community photovoice project planning. Each group will contain ten YBMSM; we plan for six groups each in the control and intervention arms. As detailed above, the intervention will consist of a group-based curriculum in program planning and HIV education, culminating in the planning and implementation of a community photovoice project.

4.4 Outcomes: The primary outcome of interest for the RCT will be social capital, as we are aiming to determine whether or not our intervention is effective in increasing social capital. We will also look at engagement outcomes, to determine whether or not increasing social capital has an impact on care engagement in our participants.

4.5 Training for all study personnel: Dr. Hussen, her mentors and collaborators all have up to date training in research ethics that they will maintain throughout the duration of the study. The graduate research assistants, coordinators and public health program associate will also receive specific training related to their assigned tasks, including but not limited to qualitative interviewing, Research Electronic Data Capture (Redcap) survey administration, and qualitative coding and analysis. They will also, importantly, be trained in the process of obtaining informed consent. Dr. Hussen and the other co-investigators have experience training and supervising staff and research assistants in all of these skills. Where possible, we will hire staff and research assistants with prior experience and/or coursework that is pertinent to this work.

4.6 Procedures for implementing and documenting informed consent: As noted above, we have requested a waiver of written consent for participation in the formative Phase I research including in-depth interviews with young Black MSM, and in-depth interviews with key informants in the community. Verbal consent scripts are included in Appendix A. Written consent will be obtained for participants in the Phase III RCT.

4.7 Plan for monitoring the informed consent/assent/permission process: All study staff who have direct contact with participants will be trained in the process of both verbal and written consent administration by Dr. Hussen. This training will include instruction on the importance and critical elements of informed consent, as well as role-playing to demonstrate proper and improper consenting techniques. New research assistants will be supervised for at least the first three consents that they do in order to observe and provide feedback; once the trainer has determined that they are able to conduct the discussion independently, they will no longer be supervised.

5.1 DATA ANALYSIS AND MANAGEMENT

5.2 Data Analysis: We will be collecting both qualitative and quantitative data during the course of this survey.

5.2.1 *Quantitative analyses:* Will be conducted using SAS or SPSS statistical software. An odds ratio plus the 95% confidence interval will be calculated to measure the degree of association between retention in care measures and total social capital (all analyses will also be computed for bonding/bridging subscales alone, as well as for item clusters focusing on different dimensions of social capital). Odds ratios will also be calculated to measure the degree of association between other risk factors (education, employment, age, depression, substance use, HIV stigma and CD4 cell count) and patient retention.

Additionally, total social capital will be compared between engaged and non-engaged patients using a two-sided two-sample t-test. Other potential risk factors will be compared between retained and non-retained patients using a chi-square test or Fisher's exact test for categorical covariates and a two-sided two sample t-test for continuous covariates. *Multivariable analyses*: Covariates significant to at least $P \leq 0.20$ in the univariable analyses will be used in multivariable logistic regression analyses. Although empirical techniques will be used to identify important covariates, theoretical expectations from our social capital conceptual framework will also augment these decisions. Interactions between covariates will be evaluated, either because suspicions are raised by clinical judgment before the analyses are performed or by statistical examination. Forward stepwise selection will be used if necessary to choose prognostic variables for a multivariable logistic regression model. The odds ratio and its 95%confidence interval will be calculated for each risk factor in the presence of others in the final model.

5.2.2 *Qualitative Data Analysis:* All digitally recorded data will be transcribed verbatim by a professional business transcription service. Qualitative data will be de-identified during this transcription process. Transcripts will then be uploaded into the MaxQDa qualitative data management software (VERBI Software, Berlin, Germany) for further processing and analysis. We will conduct thematic analysis using a combination of inductive and deductive coding. In *deductive coding*, we will apply pre-determined codes from our theoretical model (*e.g.* collective efficacy) to segments of text that correspond to each theme. In *inductive coding*, we will elicit themes that emerge from the text but were not previously considered (for example, *church community* could come up as a recurring theme among several participants and be added to our code lists). Once the list of themes has been created, we will create a codebook listing the codes and strict definitions to delineate which passages should be labeled with a certain code. The two graduate research assistants (GRAs) will each code 5 transcripts in parallel to determine inter-coder reliability. If any significant disagreements arise in coding, the entire research team will discuss each discrepancy and come to a consensus in order to finalize the codebook. The GRAs will then split and code the remainder of the transcripts. This coding will facilitate further analysis of the transcripts by comparing cases and summarizing comments under each code across participants.

Data collection:

Phase 1- *In-depth interviews with YBMSM and key informants:* All interviews will take place in a private and quiet room within the IDP clinic or in the case of key informants, at the location of their choosing. Dr. Hussen has extensive experience conducting such interviews in the clinic for prior research studies and has found this location to be acceptable and comfortable for participants. Interviews will be conducted by a graduate research assistant who will be trained in qualitative methods and interviewing techniques. All interviews will be digitally recorded for subsequent professional transcription. Written informed consent will be obtained before beginning the interview. Interviews will be expected to last approximately 60-90 minutes each. All digitally recorded data will be transcribed verbatim by a professional business transcription service. Qualitative data will be de-identified during this transcription process. Transcripts will then be uploaded into the

MaxQDa qualitative data management software (VERBI Software, Berlin, Germany) for further processing and analysis.

Phase 1- *social capital surveys:* this data was collected as part of our pilot work prior to the award period. It has already been de-identified and is ready for analysis.

Phase 2 and 3*-EMR extraction*: Viral load values and appointment attendance data will be extracted from the participants' electronic medical records (EMR) to determine retention and viral suppression outcomes. Clinical data will be entered directly into the Redcap database via a secure online form by graduate research assistants. This will be done at the baseline and 10 month time points.

Phase 2 and 3*-surveys:* In addition to attending the intervention sessions, participants in both arms will be asked to come to the IDP clinic to participate in three study visits: One at baseline before starting the intervention (0 months), immediately after completing the intervention (around 1 month), 4 months, and a long term follow-up at 10 months after enrollment. The main purpose of these visits will be to complete a survey using the Research Electronic Data Capture (Redcap) online survey platform on an electronic tablet. The Redcap survey will contain our MSCS and will be used to measure change in social capital between the pre- and post-intervention periods. We will also verify the participants' most recent medical care facility (since the last visit) and obtain the participants' signatures on medical record release forms to facilitate abstraction of data on engagement outcomes.

5.3 Data Entry, Editing and Management:

All survey and clinical data will be entered into a password protected, HIPAA compliant RedCap database. The database will be accessible only to the study team. Any subsequent datasets that are exported for analysis will be stripped of identifying information and will only be linked by a participant ID number.

In terms of identifying discrepancies, some of this will be done prospectively by building quality checks into the Redcap data collection system—for example, if certain data do not line up between the baseline and follow up surveys (*e.g.* participant's date of birth), participants will be prompted to re-enter their answers to that question. Once per month, data will be reviewed in more detail for potential errors. We will ask our biostatistician to conduct descriptive analyses in order to help us identify outliers and return to the original data source as needed to confirm outlying values.

Qualitative interviews will be transcribed verbatim. Identifying information (names) will be taken out at the time of transcription. Files will be kept in a secured shared drive (Emory Box or equivalent) for access by study staff only.

5.4 Provisions for protecting privacy:

Breach of privacy is a concern in this study as identifying information/personal health information will be collected as part of the data collection process. Additionally, efforts to

maximize retention will also include maintaining a database of participants' phone numbers and email addresses. In order to minimize the risk of a privacy breach with any of these files, participants will be assigned a subject ID number which will be used to identify them in the database. Only one file will link the subject ID number to the participants' medical record number, and all files will be password protected, kept on a secure server, and only accessible to the study team. Study files will be kept in password protected files within HIPAA compliant shared drive folders only (e.g. Emory Box). Any paper documents (such as signed informed consent forms) will be kept within a locked file cabinet in the PI's locked office accessible only to key research staff.

5.5. Information management and analysis software:

Data will be collected and stored electronically using the RedCap (Research Electronic Data Capture) program. RedCap is a secure web application for building and managing online surveys and databases. It is compliant with the requirements of HIPAA and therefore ideal for the collection and storage of personal health information such as that which we will be collecting here.

Software for data analysis will include statistical software (SAS, SPSS) as well as qualitative data management software (MaxQDa). We will de-identify all qualitative and quantitative datasets before beginning analyses and will only maintain the de-identified datasets once data collection is completed.

5.6 Quality control/assurance:

All data will be collected by trained staff members. Dr. Hussen will assume primary responsibility for training and supervision of research staff administering the recruitment, informed consents, and Redcap online questionnaires. Staff will meet for weekly supervision with Dr. Hussen and her mentors to discuss research protocol and logistical issues, as a way to allow for discussions of adverse events and promote maintenance of study integrity. Data will also be checked periodically for consistency and quality, as described in the *Data entry, editing and management* section above.

5.7 Bias in data collection, measurement and analysis

There is potential for bias in data collection, measurement and analysis in this study, which we will make every effort to curtail. Bias in *data collection* is the most likely to be a problem in our study. Selection bias in terms of our initial qualitative interviews (Phase I) and RCT participants could occur, as those YBMSM more interested in our project may already be likely to have higher levels of social capital and be more engaged in care. Given this concern, we propose to expand beyond recruiting at CBOs and in the clinic, and also recruit in more general community settings and online. In terms of *measurement*, our primary outcome will be measured using the MSCS, which has only had limited use in the YBMSM population. Although our preliminary analyses have shown good reliability in other YBMSM samples, it will be important to continue to examine the performance of this measure in this population. Finally, in terms of *analysi*s, the qualitative analysis is prone to bias given the inherent subjectivity in qualitative research. In order to counteract this, we will utilize a team approach to qualitative coding and interpretation, and we will

undertake member checking with our YCAB to ensure that our interpretation of our qualitative data is consistent with their general experiences.

5.8 Intermediate reviews and analyses

As this is not a clinical trial with potential for physical harm, it is unlikely that any interim analyses of efficacy (significant differences in social capital improvement between the two arms) would cause us to halt the trial prematurely (either for no benefit or significant benefit from the social capital intervention). However, there are other reasons to conduct interim reviews and analyses as the trial progresses; namely: to review comparability of the intervention and control arms, to review retention and participant accrual rates, and to review quality of the data. We will plan to review our enrollment data on a weekly basis; our project coordinator will generate reports of numbers enrolled and rate of completing follow-up visits and present them at our weekly team meeting. Our biostatistician will also generate summaries of our enrollment, retention, and baseline survey responses every 3 months. Additional analyses may be undertaken for the purpose of presentation in national and international scientific meetings.

5.9 Limitations of study:

There are several limitations to this study. Recruitment and retention have the potential to be challenging among YBMSM living with HIV. In terms of initial recruitment, subjects who are newly diagnosed or re-engaging in care may decline participation due to challenges coping with new information, denial and/or grief in response to their new diagnosis. Experienced personnel and dedicated coordinators will be used to maximize recruitment. We are also planning to recruit from a wide range of venues including the Grady IDP clinic and our partnering community-based organizations. If enrollment is still inadequate, which is unlikely, we also have relationships with other clinical sites in Atlanta that care for HIV-positive YBMSM aged 18-29 (the Emory Midtown Hospital HIV clinic, Atlanta Veterans Administration Hospital, Fulton County Health Department) and could look into expanding recruitment to those sites.

5.10 Identifying, managing, and reporting adverse events:

Study staff will be instructed to notify the PI immediately via phone or pager if there is any adverse event, whether or not they perceive it to be related to study participation. The project coordinator will then take the responsibility of reporting to the Emory IRB within 24-48 hours. Additionally, the project staff member who witnessed the event will complete an Adverse and Negative Events Form (Appendix H) that includes the date, a description of the event, duration, severity, actions taken to remedy the negative event (including professional referrals).Adverse events will also be reported to the CDC.

5.10.1 Specific procedures for handling reports of psychological distress:

There is a risk of uncovering information about psychological distress during the qualitative interviews, as questions about social support networks (or lack thereof) and coping with HIV can be sensitive topics for some. Prior to beginning the study, research staff will receive sensitivity training from mental health providers at the IDP clinic, in order to be knowledgeable of psychological occurrences that require

intervention by a mental health professional. Any assessment of a potential psychological emergency during the course of the trial will result in the patient being transported to the Crisis Intervention Service unit at Grady Hospital, a 24-hour psychiatric emergency service with the ability to evaluate and stabilize patients. If less emergent emotional distress is noted, staff will be equipped with pamphlets listing mental health resources in the community and will assist with referrals as needed.

6.0 DISSEMINATION, NOTIFICATION AND REPORTING OF RESULTS

Dissemination of the results in the scientific and local community is a critically important part of this process. We plan a three pronged approach that includes: (1) *Community meetings* at the midway point and at the end of the project. At these meetings (which we also plan to stream as a webinar), we will invite community members to hear about the status of our project, to ask questions and to provide feedback on next steps. We will invite all of the key informants from Phase 1 to these meetings and enlist the help of the YCAB in advertising to the audience who would find it most relevant. (2) *Scientific publications:* We will publish interim and final results of each phase in peer-reviewed publications. Where possible, we will try to publish in open-access journals to facilitate dissemination to those outside of academic institutions. (3) *Presentations at Scientific meetings*: We will also present interim and final results at national and international meetings such as the American Public Health Association and International AIDS Society meetings.

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Appendix A: B6 Addendum

A result of phase 1 was the development of Brothers Building Brothers By Breaking Barriers (B6), a two-day, 10-module group-level intervention. B6 does not focus exclusively on HIV, but rather takes a more holistic approach to supporting youth and developing resilience. The B6 intervention modules aim to develop resilience at the individual level (exploration of black gay identity, development of critical self-reflection and coping skills), social network level (exploring strategies for navigating family relationships) and community level (developing strategies for navigating clinical spaces and plans for community participation). Most intervention activities are interactive, in order to facilitate new social network connections (social capital) within intervention groups. In summary, our intensive CBPR approach resulted in a novel, culturally-specific intervention designed to enhance resilience by augmenting social capital among YB-GBMSM living with HIV.

Based on the aforementioned qualitative content analyses, a condensed list of key programmatic recommendations was created for incorporation into the intervention (Table 1). Participants had favorable reactions to the idea of a social capital-based resilience intervention for YB-GBMSM living with HIV. The most commonly cited recommendation was to ensure that the intervention addressed the holistic health and well-being of the participants, and did not focus too narrowly on HIV-specific content. Participants also gave feedback about the manner in which the intervention should be delivered, citing the importance of balancing entertainment with the educational objectives.

Table 1. Key Recommendations from Qualitative Interviews

Content

- Find a way to treat the whole person
- Teach about finances, school, health, wellness
- Empower participants with skills to get support they need
- Raise awareness and pride about black gay culture and history
- Address stigma, internalized homophobia
- Find ways to create connectedness between YB-GBMSM
- Refer participants to other resources as needed, particularly mental health

Approach

- Engage participants, make activities interactive and entertaining
- Group discussions
- Be nonjudgmental, sex positive, don't try to change people
- Consider judicious use of social media
- Meet participants where they are in terms of interest in HIV care engagement

Using a process informed by Intervention Mapping, which is a planning approach that combines theory and evidence as the foundation for taking an ecological approach to assessing and intervening in health problems and engendering community participation (Eldredge, L. K. B., Markham, C. M., Ruiter, R. A., Kok, G., & Parcel, G. S. (2016). Planning health promotion programs: an intervention mapping approach. John Wiley & Sons.), we combined the qualitative findings, theoretical constructs and YCAB input to develop an intervention outline focused on the following overarching goals: (1) exploration of one's self and identities; (2) building bonding capital; (3) building bridging capital; and (4) sustaining connections. We used an Intervention Mapping- informed process to align the theoretical constructs of social capital and the feedback from the qualitative findings with specific intervention components and activities. Table 2 displays the intervention content and the learning goals and objectives for each of the 10 modules of the intervention.

Table 2. Intervention Course Agenda

Day 1	
Session 1	Welcome to B6
Module 1: Set the Stage	Welcome/Introductions Brotherhood Agreement Brother Bingo
Module 2: Who's on your team?	Social Capital Presentation (together we have more) Bound By Barriers
Session 2	Building Myself
Module 3: Who am I?	Worth a Thousand Words On the Flip Side Affirmation Activity
Module 4: Communicating my Needs	Love Languages Assertive Communication (Passive/Aggressive)*
Module 5: Critical Reflection/Problem Solving	Critical Reflection: What? So What? Now What?* What would you do?
Session 3	Building Bridges
Module 6: Breaking Barriers: Relationships	Who you gonna Call? Acting Out B6 Trivia Review Closing

Day 2	
Session 3 Continued	Building Bridges
Module 7: Breaking Barriers: Professional Settings	Welcome Back! Work/School Life (Critical Reflection/Problem Solving) Rep Your Clinic
Session 4	Building Bonds

Module 8: Black Gay Community	What is Black Gay Community? Role Models/Heroes Jeopardy
Session 5	Staying Connected
Module 9: Connecting the Dots	Goal Setting * Using my Social Capital (Support Web) Building the Other Brother
Module 10: My Social Capital	30 Day Challenge So I know it's real Conclusion