

**Brothers Building Brothers by Breaking Barriers for Telehealth
Delivery (Tele-B6)
STUDY00003404**

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PROTOCOL TITLE: Brothers Building Brothers by Breaking Barriers for Telehealth Delivery (tele-B6)

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1	11/8/21	Addressed comments
2	12/7/2021	Clarified role of THRIVE SS
3	11/3/2025	Adjusted follow up survey timepoints

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1. Study Summary

Study Title	Brothers Building Brothers by Breaking Barriers for Telehealth Delivery (tele-B6)
Study Design	Three phases: Phase I: Adaptation and Modification of Intervention Phase II: Pilot RCT Phase III: Community Implementation
Primary Objective	To adapt B6 for telehealth delivery, conduct a pilot randomized controlled trial to evaluate feasibility, acceptability, and safety of the <i>tele-B6</i> intervention, and evaluate the process of implementing <i>tele-B6</i> within the context of a community-based organization.
Research Intervention(s)/Interactions	Subjects will participate in synchronous, online discussion sessions via videoconference for two hours per week over a six-week period. Sessions will include engaging educational components and interactive activities including discussions of case scenarios and sharing of personal experiences where desired. At the end of each videoconference session, participants will be asked to complete a brief session evaluation form in which they will rate the content, facilitation and overall experience for the week
Study Population	18–29-year-old Black, gay, bisexual, and other men who have sex with men living with HIV in the Atlanta Metro area.
Sample Size	Phase I: N=6 for convenience sample, pilot run through Phase II: N=60, with 30 randomized to each group (waitlist control and intervention) Phase III: N=15 staff members/volunteers
Study Duration for individual participants	Phase I: 5-week intervention period only Phase 2: 6 months Phase 3: 2 years

Funding Source (if any)	NIH
External Collaborators	<p>The University of Michigan will not directly enroll or perform intervention on participants at their own site, and will not have access to any identifiable data collected during the study.</p> <p>██████████ is a clinical psychologist and public health professor with extensive experience in community-engaged intervention development among sexual minority youth. ██████████ has worked closely with Hussen for over eight years, including on the development of B6. He will attend study team meetings to advise on intervention adaptation, study protocols, troubleshooting, and qualitative analyses. ██████████ will not interact directly with any research participants or raw data.</p> <p>██████████ is a social psychologist with substantial experience in community-engaged intervention development with people living with and at-risk for HIV, and has served as the lead quantitative data analyst for several NIH-funded pilot intervention studies. She will be the lead biostatistician on the study but will work exclusively with de-identified data.</p>

2. Objectives

Our *long-term goal* is to improve engagement across the HIV continuum of care (HIV-CoC) by enhancing individual- and community-level resilience processes among young Black gay, bisexual and other men who have sex with men (YB-GBMSM) living with HIV. To this end, we used community-based participatory research methods to develop **Brothers Building Brothers by Breaking Barriers (B6)**, a novel group-level intervention designed to affirm intersectional identities and augment social capital among YB-GBMSM. The goal of this current study is to adapt and pilot B6 for *telehealth delivery* (creating *tele-B6*) within the context of an established community-based organization (CBO), as a strategy for enhancing feasibility and scalability prior to a larger efficacy trial.

Specific Aims:

Aim 1: To adapt B6 for telehealth delivery, in collaboration with YB-GBMSM, community partners, and an advisory panel of subject matter experts. We will translate our culturally-grounded, theory-based content into a series of synchronous videoconference discussions with accompanying online resources, using the ADAPT-ITT framework.⁴³

Aim 2: To conduct a pilot randomized controlled trial to evaluate feasibility, acceptability, and safety of the *tele-B6* intervention among YB-GBMSM living with HIV in Atlanta. We will recruit N=60 YB-GBMSM (randomized to intervention or waitlist control groups) into a pilot trial and utilize a mixed-methods approach to examine feasibility, acceptability, and safety of *tele-B6*. We will also explore evidence of preliminary intervention effects on identity beliefs, social capital, stigma, and HIV-CoC engagement.

Aim 3: To evaluate the process of implementing *tele-B6* within the context of a community-based organization. We will draw on the Consolidated Framework for Implementation Research to analyze staff effort and intra-organizational processes relating to *tele-B6* implementation within our partner CBO.

3. Background

HIV continues to disproportionately impact young Black gay, bisexual, and other men who have sex with men (YB-GBMSM) at staggering rates; by age 30, an estimated 40% will be living with HIV.⁴⁷ Thirty-six percent of Black GBMSM diagnosed with HIV in 2016 were aged 13-24 years; 39% were aged 25-34.¹¹ Although current HIV treatments effectively prevent morbidity and mortality, YB-GBMSM are at high risk for disengagement across the HIV Continuum of Care (HIV-CoC), leading to lower rates of engagement including linkage to care, retention in care, medication adherence, and viral suppression¹² relative to other demographic groups.¹³⁻¹⁶

YB-GBMSM encounter multiple barriers to engaging in HIV care, as a direct result of racism, homonegativity, and HIV stigma operating at structural, interpersonal and intrapersonal levels.¹⁻⁹ Despite these known disparities, there are few evidence-based approaches for improving care engagement with people living with HIV, and very few have specifically addressed the social, cultural, and developmental contexts of living with HIV for YB-GBMSM.¹⁷ There is an urgent need for evidence-based interventions designed specifically for YB-GBMSM living with HIV, to improve HIV-CoC outcomes and ultimately reduce morbidity, mortality, and HIV transmission.

The few existing interventions to improve HIV-CoC outcomes for youth, while useful, often target individual-level behavior change without addressing the psychosocial mechanisms through which larger social contexts influence clinical outcomes.^{18, 19} *Resilience*, at both individual and community levels, can buffer the negative effects of structural racism, homonegativity, and HIV stigma on HIV-CoC outcomes.^{20, 21} Individual-level resilience processes include *affirming identity beliefs* relating to one's own race, sexuality, and HIV status; these can enhance care engagement among youth living with HIV.²²⁻²⁴ Community-level resilience processes that improve HIV care engagement include the utilization of *social capital*, defined as the sum of resources that can be gained from a person's social network.²⁵⁻²⁷

Brothers Building Brothers By Breaking Barriers (B6), designed with and for YB-GBMSM living with HIV, is an acceptable, culturally-specific intervention designed to build resilience processes through intersectional identity affirmation and enhancement of social capital. Using

a community-based participatory research (CBPR) approach, we initially developed B6 as an in-person intervention.²⁸ We conducted a pilot trial with N=72 participants; N=48 were assigned to the B6 intervention and N=24 underwent a comparison intervention (matched for time and attention) that did not focus on identity or social capital. B6 was delivered in a single day intensive session and included 14 interactive modules addressing a host of issues including Black gay identity, understanding and improving social capital, and navigating logistical barriers to HIV care. Our initial pilot found:

- 1) **The intervention was highly acceptable to YB-GBMSM living with HIV.** Participants described specific benefits of B6, including bolstered self-acceptance of gay identity, improved communication with family and partners, and lasting social connections.
- 2) **We have preliminary evidence of favorable effects of B6 on participants' self-reported HIV stigma, internalized homonegativity, and engagement in HIV care.** Our pilot trial was not powered for efficacy; however, effect size analyses suggest several positive results of the intervention. Three months after participation, B6 intervention participants had lower reported HIV stigma and internalized homonegativity, and fewer missed HIV care appointments than at baseline; these effects were stronger in B6 than in comparison group participants.
- 3) **The feasibility of conducting the intervention in-person was limited by challenges with recruitment and retention.** Recruitment and retention of participants were significant barriers to intervention feasibility. Although we were able to identify YB-GBMSM living with HIV who initially expressed interest and agreed to participate, show rates on the actual day of intervention were suboptimal. Previously confirmed individuals often mentioned transportation or work commitments as barriers to participation in the full-day, in-person intervention. To enhance feasibility and scalability of B6, we will therefore need to establish the effectiveness of alternative delivery methods such as *telehealth delivery* and/or delivery within the context of *community-based organizations* (CBOs).

Overall, in our initial pilot trial of B6 as an in-person intervention, we found high levels of acceptability and satisfaction, as well as preliminary evidence for favorable effects on internalized homonegativity, HIV stigma, and HIV care engagement. However, we encountered limitations to feasibility with the in-person format.

Telehealth delivery of interventions is scalable, feasible, and acceptable to youth living with HIV. Nearly 100% of US youth aged 18-29 own a mobile phone, and 96% own a smartphone.⁸⁵ Researchers have increasingly turned to digital health approaches, including development of mobile apps, social media campaigns, and telehealth to deliver youth-focused interventions targeting engagement across the HIV-CoC.⁸⁶⁻⁹¹ *Telehealth*, referring simply to the use of electronic communication technologies to support health interventions over a distance,⁹⁶ has been scaled rapidly in medical settings in the wake of the COVID-19 pandemic, including among youth living with and at risk for HIV.⁹⁷⁻⁹⁹ Telehealth also has demonstrated acceptability

for behavioral intervention delivery in prior studies with these populations.¹⁰⁰⁻¹⁰² These studies suggest that telehealth is a potentially efficacious, acceptable and scalable strategy for intervention delivery to YB-GBMSM.

Our scientific premise is that telehealth delivery and CBO-based implementation of a resilience-focused intervention will enhance social capital, affirm identity beliefs, and ultimately improve engagement across the HIV-CoC for YB-GBMSM.

4. Study Endpoints

Primary Outcomes: Acceptability, feasibility, and safety. To assess *acceptability*, we will modify previous intervention satisfaction evaluation surveys and administer them at the end of each group discussion. We will also assess acceptability using data on participants' reactions to various program components gathered from the facilitators' intervention logs. Finally, we will conduct exit interviews with selected participants at the end of the six-week intervention period, in order to gather qualitative feedback about the structure, content, and experience of the intervention. To assess *feasibility*, we will monitor rates of outreach, recruitment, eligibility, enrollment, attendance, retention, and assessment completion. Based on calculations for enrollment and participation above, our recruitment goal will be to identify at least 13 eligible YB-GBMSM per month, to achieve intervention completion rates of $\geq 80\%$ of group sessions completed, to maintain high intervention fidelity (goal: $\geq 90\%$ fidelity on checklists), and to ensure adequate retention across the follow-ups (goal: $\geq 80\%$). Fidelity assessments will also be an important part of feasibility assessments: *tele-B6* facilitators will complete a structured intervention log after each session to assess fidelity to intervention, time needed, and feasibility of delivering the intervention curriculum as designed. To assess *safety*, we will monitor adverse events, including psychological or physical events occurring over the course of intervention participation.

Exploratory Outcomes. Although the primary aims of this study are to assess acceptability and feasibility, we will also assess HIV-CoC outcomes, as well as key mediators that are being targeted in *tele-B6*. Selection of measures will be guided by the relevant literature and our preliminary studies. Our eventual target outcome (in our subsequent, fully-powered study), *HIV Care Engagement* will be measured in terms of *viral load suppression* (defined as viral load measurement below 200 copies/mL at the most recent measurement before baseline, and at a data abstraction point at least 6 months post enrollment) and *retention in HIV care*, measured by missed visits before and after intervention participation. Missed visits are a validated measure of retention;¹⁴⁸ additionally, we will not be able to use the Department of Health and Human Services (DHHS) retention measure (≥ 2 visits in 12 months, at least 3 months apart)¹⁴⁹ due to the limited follow-up period. We will use previously validated scales with excellent documented reliability among our study population to measure key constructs in our conceptual model (structural racism and discrimination, logistical barriers, intersectional stigma, minority stress) and the resilience processes (identity affirmation and social capital) targeted in *tele-B6*. The

aforementioned qualitative exit interviews will also include domains assessing model constructs and resilience processes in addition to acceptability and satisfaction.

5. Study Intervention/Design

The study will involve three distinct phases, each corresponding to one of the research aims.

Phase I: we will adapt the original B6 intervention for telehealth delivery, based on the ADAPT-ITT framework and with the input of the YAB, THRIVE SS, and EAP. The goal of this phase is to convert our B6 content into a telehealth intervention (“tele-B6”) that can be delivered 100% remotely, while still retaining the personal connections and group engagement of the original in-person intervention.

Phase II: we will conduct a pilot randomized controlled trial with goal enrollment N=60 (with 30 subjects in each group, intervention and waitlist control) to evaluate feasibility, acceptability, and safety of the adapted *tele-B6* intervention. We will also conduct in-depth interviews (IDIs) with a subset of participants.

Phase III: we will evaluate the process of implementing *tele-B6* within the context of a community-based organization, THRIVE SS.

6. Procedures Involved

Phase I (adapt B6 for telehealth delivery, in collaboration with a youth advisory board (YAB), community advisors (THRIVE SS), and an advisory panel of subject matter experts (EAP)).

Adaptation Process. We will draw on Wingood and DiClemente’s ADAPT-ITT framework⁴³ to guide intervention modifications (**Table 1**). ADAPT-ITT generally describes the process of adapting interventions for new populations – here, the target population will remain unchanged; however, the study settings and intervention delivery methods will change. We have already begun first two Steps (**A**ssessment of population priorities and **D**ecisions about what content to adapt), and will also work in a collaborative and participatory manner with our YAB to decide on further modifications. In the next step (**A**dministration of the intervention), we will pilot individual *tele-B6* modules with the YAB. We will then **P**roduce a draft of the intervention manual and solicit feedback from our **T**opical experts (the EAP). We will **I**ntegrate this feedback into the adapted intervention and re-present the newest version to our YAB, THRIVE SS and the EAP for feedback. At this point, we will have completed the adaptation process and will **T**rain study staff in implementation in preparation for **T**esting (**Aim 2**).

Intervention Format and Content. Table 2 depicts an overview of existing B6 content and proposed modifications for tele-B6. Whereas the original B6 intervention was delivered in person over a single day, the main content in *tele-B6* will be delivered via a series of six videoconference group discussions (two-hour sessions delivered weekly for six weeks), accompanied by intervening communication and brief, self-paced activities to be completed by participants on their own time. We have found this format to be engaging and feasible in ongoing work with our YAB through the COVID-19 pandemic. This modification is based on feedback from original B6 participants who expressed the desire for continued engagement, as well as prior research suggesting that increasing intervention intensity (i.e., length and frequency of engagement) has the potential to increase efficacy.¹³⁵ We will add a password-protected section to the THRIVE SS website (www.thrivess.org), including: (1) Links to password-protected Zoom (or similar platform) sessions for weekly synchronous, online discussions; (2) educational resources (videos, infographics, case scenarios) for asynchronous content delivery between weekly sessions; (3) online discussion forums to facilitate communication between participants and with study staff; (4) links to community resources.

Table 1. Adaptation Process for Creation of *Tele-B6* intervention

ADAPT-ITT Steps	Timing	Methodology
1) <u>A</u> ssessment of priorities	Preliminary Studies (pre-proposal)	Reviewed extensive preliminary data on social capital, identity, resilience, and HIV care engagement; key informant interviews
2) <u>D</u> ecisions about content to adapt	Begun pre-proposal, Months 1-3	B6 intervention already created. Will convene YAB for iterative feedback sessions re: modifications.
3) <u>A</u> dministration	Months 1-3	Pilot testing individual modules with the YAB to inform decisions
4) <u>P</u> roduce	Months 3-6	Revise current manual, produce supplementary online materials
5) <u>T</u> opical Experts	Months 6-9	Individual and group meetings with YAB, THRIVE SS and the EAP
6) <u>I</u> ntegrate Feedback	Months 9-12	Analyze feedback from YAB, THRIVE SS, and EAP; revise manual
7) <u>T</u> rain Study Staff	Months 9-12	Practice sessions with YAB & pre-RCT full pilot with convenience sample.
8) <u>T</u> est	Years 2-3	Pilot RCT (Aim 2)

Table 2. Intervention Content with Proposed Adaptations from Original In-Person B6 to *Tele-B6*

Timing	Target Constructs	Module Title (in original B6)	Module Goals (from original B6)	Potential Adaptations in <i>tele-B6</i> (subject to change)
Week 1: Introductions		Set the Stage	Introduce facilitators and participants, set expectations and create a safe space	Convert to online group discussion (synchronous)

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	Social Capital	Introduction to Social Capital	Explain the theoretical foundation of the intervention to participants	Convert to group discussion and create infographics for website.
	Identity Affirmation	Who am I? Multiple Identities	Identify the ways in which multiple identities (e.g., gay identity, Black identity, HIV-positive identity) interact	Convert to online group discussion (synchronous)
Week 2: Exploring Self	Social Capital	Breaking Communication Barriers	Reflect on personal communication styles and any barriers to effective communication	Convert to educational materials for posting on website, create pre-/post-quiz
	Coping with Minority Stress	Critical self-reflection and coping skills	Reflect on how individual actions impact others; discuss common stressors and positive coping strategies	Convert to online group discussion (synchronous)
Week 3: Building Bonds	Identity Affirmation	Black Gay Slay: A History	Gain appreciation for the historical contributions of Black gay men in society	Create educational materials (e.g., brief video) to post online
	Social Capital	Black Gay Community	Explore perceptions, stereotypes and diversity within the Black gay community	Convert to online group discussion (synchronous)
Week 4: Building Bridges Part 1	Social Capital	Navigating Family	Gain tools to develop healthier relationships with family (birth or choice)	Convert to online group discussion (synchronous)
	Coping with Racism/Discrimination	Navigating Professional Spaces	Build skills for succeeding in professional arenas and cultivating relationships with colleagues and supervisors	Convert to online group discussion (synchronous), post case studies on website
Week 5: Building Bridges Part 2	Coping with Racism/Discrimination	Navigating Clinical Spaces	Enhance skills for navigating healthcare settings, share strategies for communicating effectively with providers	Convert to online group discussion (synchronous), post case studies on website
	Social Capital	Navigating Intimate Relationships	Reflect on intimate relationships; learn strategies to improve partner communication.	Convert to online group discussion (synchronous), post case studies on website
Week 6: Sustaining Connections	Individual Resiliencies	Individual Goal Setting	Set short and long-term goals for career, relationships, health.	Create educational materials (e.g., worksheet) to post online
	Social Capital	Community Action	Learn strategies for activism and formulate community action plans.	Convert to online group discussion (synchronous)

		Conclusions	Closing ceremony, distribution of a compilation of community resources	Create list of community resources to post on website
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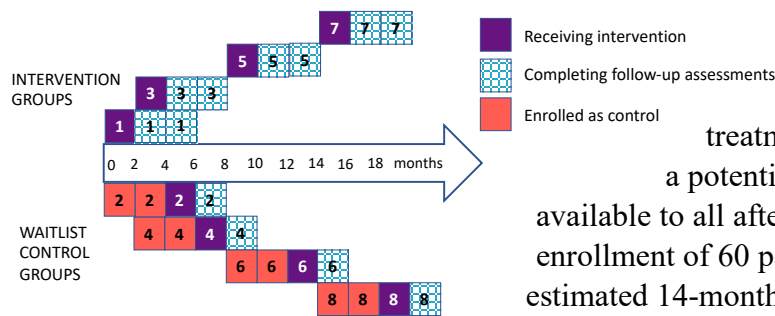
Iterative CBPR Modification Process. Throughout the ADAPT-ITT process, we will use an iterative participatory process whereby study staff will deliver each module to the YAB, followed directly by a collaborative session where they will solicit feedback and re-design recommendations for that specific module’s content and format. The potential strategies for adapted intervention delivery depicted in **Table 2** are subject to change. YAB members will be encouraged to take notes during the administration of each module in order to provide detailed and specific feedback. Jones and Newman will also use Zoom’s shared screens and annotation functions to record concerns and recommendations during the collaborative feedback and re-design sessions. These sessions will also be audio-recorded for further potential review. Field notes (with both observational and interpretive elements) will be taken during the course of each feedback and re-design session by research assistants observing these sessions. At the end of each session, Jones, Newman and the research assistants will engage in a process of critical reflection regarding the group, and develop combined reflection notes based on these conversations. Once all modules have been reviewed using this process, the study team will meet to make final decisions about modifications. We will then create the new intervention manual, and work with the YAB to create new online content. The YAB, EAP and members of THRIVE SS will review the *tele-B6* manual, and make recommendations for changes during individual and group feedback meetings. Prior to commencement of the RCT, we will also recruit a separate convenience sample to conduct a pre-RCT pilot test of the intervention, so as to uncover potential implementation challenges and make any necessary modifications to prior to the RCT.

Facilitator Training. Jones and Newman will be the two lead facilitators of *tele-B6* (subject to change; *any facilitators would be trained extensively prior to the intervention*). Although they are intimately familiar with the original intervention content, training will be needed to standardize approach between the two facilitators, and to practice intervention delivery via videoconference. Jones and Newman will practice delivering modules with the YAB, and also during facilitation of the pre-RCT pilot referenced above. During this time, other team members will observe and note differences to be resolved prior to the RCT. During these observation sessions, we will refine an *intervention log* (a checklist modified from original B6) that we will use to measure fidelity during the RCT.

Phase II (a pilot randomized controlled trial (RCT) to evaluate feasibility, acceptability and safety of the *tele-B6* intervention among YB-GBMSM living with HIV in Atlanta.)

Study Design. We will conduct a pilot RCT, where upon enrollment participants will be randomized to either the intervention or to a wait-list control condition, in which participants will

Figure 2. Waitlist Control Study Design



also receive the intervention after a four-month waiting period (Figure 2). We chose a wait-list control design to safeguard ethical

treatment of participants by ensuring that a potentially impactful intervention will be

available to all after a brief waiting period. Rolling enrollment of 60 participants will take place over an estimated 14-month time period; group assignment will

occur as soon as sufficient participants are enrolled for two

groups. As described above, the *tele-B6* intervention includes six group sessions delivered over the course of six weeks. Survey assessments for the intervention group (first phase) will be conducted at enrollment (baseline), 2 months (immediate post-intervention survey), 4 months (interim-survey, post-intervention) and 6 months (endline). The second phase of the study, the delayed intervention (waitlist control) phase, provides an opportunity for the control arm to receive the intervention and simultaneously to (1) follow intervention arm participants for a further 2 months to assess the persistence of intervention effects, and (2) replicate main trial findings utilizing wait-list control data. Wait-list control participants will be assigned to a group for initiation of the full intervention beginning at month 2 after their enrollment (i.e., beginning after they, and their corresponding intervention group, have completed their intervention and one follow-up survey). Wait-list control participants will complete surveys at enrollment (baseline), 2 months (pre-intervention), 4 months (pre-intervention), and 6 months (immediate post-intervention).

Participant Experience. We will obtain electronic informed consent in one-on-one meetings conducted either via videoconference or in person prior to the first intervention visit. Participants will then complete the baseline REDCap survey and be provided with the schedule of *tele-B6* sessions and instructions on how to log on to the videoconference meeting at the pre-specified time. On the days of the *tele-B6* sessions, we expect that most will log in from home; however, THRIVE SS has also agreed that participants can use their facilities for computer and/or wifi access if needed. YB-GBMSM will participate in synchronous, online discussion sessions via videoconference for two hours per week over a six-week period. Sessions will include engaging educational components and interactive activities including discussions of case scenarios and sharing of personal experiences where desired. At the end of each videoconference session, participants will be asked to complete a brief session evaluation form in which they will rate the content, facilitation and overall experience for the week, after which they will receive a \$25 electronic gift card. In the intervening week between sessions, participants will be asked to view additional resources and activities housed on the website in preparation for the following week. They will also have the opportunity to chat with each other and with facilitators on online discussion forums hosted on the website – these will be unstructured but moderated by study staff to ensure that there is no inappropriate content (i.e., bullying, harassment). Participants will retain access to the website after *tele-B6* completion, and will also be formally linked to

THRIVE SS for additional support if they are not already members. The participants will then be emailed/texted links to follow-up REDCap surveys to complete follow-up assessments.

Evaluation Strategy. We will utilize a mixed-methods approach to evaluate our intervention and assess our primary and exploratory outcomes (**Table 3** below). Data sources will include intervention logs, adverse event reports, periodic electronic surveys, qualitative exit interviews, and electronic medical record (EMR) data.

Table 3. Aim 2 Measurement Priorities

	Constructs	Assessment Strategy	Measures (where applicable)	Timing
Primary R34 Outcomes	Acceptability	Qualitative Interviews	Open-ended questions adapted from original B6 exit interview guide	Exit interviews
		Surveys	Post-session eval forms (adapted from original B6)	After each group session
	Feasibility	Recruitment rates	Rates of participation from screened and eligible participants	Continuous
		Retention	Attendance logs	Continuous
		Intervention Fidelity	Structured intervention logs (adapted from original B6)	Continuous
	Safety	Adverse Events	Adverse event tracking forms	Continuous
Model Constructs	Structural Racism and Discrimination	Surveys	Measures of socioeconomic status, demographics Material resources scale ¹⁴²	0, 2, 4, 6months
	Intersectional Stigma	Surveys	Everyday Discrimination Scale ¹⁴³ HIV Stigma Scale ¹⁴⁴ Internalized Homonegativity Inventory ¹⁴⁵	0, 2, 4, 6months
		Qualitative Interviews	Open-ended questions adapted from original B6 exit interview guide	Exit interviews
	Logistical Barriers	Surveys	Zip code to derive neighborhood measures	0, 2, 4, 6months
		Qualitative interviews	Open-ended questions adapted from original B6 exit interview guide	Exit interviews

	Individual Resilience Process: Identity Affirmation	Surveys	Multidimensional Model of Black Identity ¹⁴⁶ Lesbian, Gay and Bisexual Identity Scale ¹⁴⁷	0, 2, 4, 6months
		Qualitative interviews	Open-ended questions adapted from original B6 exit interview guide	Exit interviews
	Community Resilience Process: Social Capital	Surveys	Personal Social Capital Scale ²⁶	0, 2, 4, 6months
		Qualitative interviews	Open-ended questions adapted from original B6 exit interview guide	Exit interviews
	Minority Stress	Surveys	Mental health measures including: Depression (CES-D) General Well-Being (GWB)	0, 2, 4, 6months
		Qualitative interviews	Open-ended questions adapted from original B6 exit interview guide	Exit interviews
Clinical Outcomes	HIV Care Engagement	Electronic Medical Record (EMR) abstraction	HIV viral load Retention in Care (missed visits)	0 and 6 months

Data Collection Procedures - Surveys. We will use REDCap to create and administer baseline and follow-up surveys of participants. Surveys will be administered at baseline, 2-, 4-, 6- month timepoints. Reminders to complete surveys will be sent via text message where needed. Survey Procedures: Surveys will primarily be conducted remotely, but can also be done in person at THRIVE SS or Emory if a participant prefers. We estimate that the surveys will take 30 minutes to complete. Best practices for web-based data collection will be employed to detect suspicious response patterns.¹⁵⁰

Data Collection Procedures - Qualitative Interviews. To evaluate B6 feasibility and acceptability, as well as descriptive accounts of any impact on resilience processes and/or conceptual model constructs, we will conduct qualitative exit interviews with a subset of participants (planned n=20 interviews). We will conduct these in-depth interviews (IDIs) with a purposively selected sample of participants, including both participants who maintained high levels of engagement and those with lower levels of engagement. Interviews will focus on experiences with the B6 intervention, and recommended improvements. IDI Procedures: IDIs will be conducted by trained study staff via Zoom. We will have participants interviewed by the staff member who was not their *tele-B6* facilitator, in order to provide space for criticism if

needed. Verbal consent will be obtained prior to each IDI, and participants will receive a \$25 electronic gift card upon completion. All interviews will be digitally recorded and uploaded to a secure server for professional transcription and analysis. Interviewers will record field notes, documenting salient themes to be explored in subsequent IDIs.

Data Collection Procedures - Clinical EMR data abstraction. To measure preliminary efficacy of *tele-B6* for improving engagement in care (defined using exploratory endpoints of care retention and viral suppression), we will abstract clinical data from the EMR. We will compare retention and viral suppression outcomes pre- and post- B6, and compare the intervention and control groups. At baseline and 6 months later, we will abstract viral load measurements as well as missed, scheduled, and attended appointments. Data will be entered into a secure REDCap database by trained abstractors (graduate research assistants), using standardized abstraction forms and manuals.¹⁵¹ For the first three months of abstraction, EMR data will be abstracted by two study team members in parallel and examined for inter-coder reliability. Differences will be discussed, and forms and manuals revised until inter-coder reliability is adequate ($\kappa \geq 0.80$). [REDACTED] are experienced in training teams on EMR abstraction for HIV-CoC outcomes.^{32, 152}

Phase III (evaluation of implementing *tele-B6* within the context of a community-based organization.)

Phase 3 seeks to answer the question, “*How can we best facilitate future implementation of tele-B6 via CBOs such as THRIVE SS?*” To begin to address this question, we will conduct a mixed-methods assessment guided by the **Consolidated Framework for Implementation Research (CFIR)**,¹⁶⁹ which synthesizes multiple theories to provide a “menu of constructs” associated with effective implementation. CFIR domains include: **(1) *Intervention Characteristics*** (i.e., perceptions of *tele-B6*); **(2) *Outer Setting*** (economic, social and political context surrounding the CBO); **(3) *Inner Setting*** (structural and cultural features within the CBO); **(4) *Characteristics of Individuals*** (staff who would implement *tele-B6*), and **(5) *Process*** (steps needed to implement *tele-B6*). We will develop brief surveys and interview guides to assess CFIR constructs (**Table 4**).

Table 4. Consolidated Framework for Implementation Research (CFIR)- guided Assessment Strategy

CFIR Construct	Description	Assessment Methods	Specific scales from which survey items will be derived; or qualitative domains where applicable
Intervention Characteristics			
Relative Advantage	Perceptions of advantage of implementation	Qualitative IDIs	Open-ended questions about whether <i>tele-B6</i> is perceived as beneficial by THRIVE SS staff
Complexity	Perceived difficulty of implementation	Qualitative IDIs	Open-ended questions about perceived difficulty of implementing <i>tele-B6</i>
	Staff effort	Electronic Logs	THRIVE SS staff working on the project will be asked to record time spent doing <i>tele-B6</i> related activities.
Outer Setting			
Client Needs and Resources	Client needs; barriers & facilitators for meeting them	Qualitative IDIs	Open-ended questions about barriers and facilitators to HIV CoC among YB-GBMSM
		Surveys	Study team to create items
External Policy and Incentives	Policies that could help/ hinder implementation	Qualitative IDIs	Open-ended questions about perceived barriers and facilitators to <i>tele-B6</i> implementation
Inner Setting			
Networks and Communications	Nature and quality of communication within the organization	Surveys	Study team to create items
		Qualitative IDIs	Open-ended questions soliciting detailed descriptions of referral and communication processes
Organizational culture	Norms, values of the specific clinic setting	Qualitative IDIs	Open-ended solicitation of description of organizational culture, descriptions of how initiatives are implemented
Leadership engagement	Commitment, involvement of THRIVE SS leadership	Surveys	Selected items: Implementation Leadership Scale (ILS) ¹⁷⁰
Characteristics of Individuals			
Knowledge & beliefs	Familiarity with <i>tele-B6</i>	Surveys	Study team will create items specific to <i>tele-B6</i> .
Self-efficacy	Individual belief in own capability to implement new	Surveys	Study team will modify items from the general self-efficacy

	interventions at THRIVE SS		scale ¹⁷¹ to measure efficacy for implementing <i>tele-B6</i>
Process			
Planning, Engaging, Executing and Evaluation	Analysis of steps taken to implement an intervention	Qualitative IDIs	Recommendations for future implementation processes and how B6 integration might fit into organizational flow.

This assessment will run in parallel with the pilot RCT procedures described for Aim 2, such that implementation challenges and successes can be identified in *real-time*.

Surveys. We will administer brief electronic surveys to THRIVE SS staff in order to assess CFIR constructs relating to implementing *tele-B6*. Surveys will be conducted every 6 months, beginning halfway through Year 1 (i.e. 6 months prior to initial *tele-B6* implementation, and then every 6 months until the end of the project period). Sample size for this portion of the study will be based on feasibility of recruitment (any staff or general members involved with the project will be invited to join); we estimate that we can enroll approximately 15-20 individuals. As in Aim 2, we will use REDCap to create and administer surveys, which will take an estimated 20 minutes to complete. Participants will have the option of completing surveys in-person or remotely. Upon completion of each survey, respondents will receive a \$25 electronic gift card.

Qualitative interviews. To evaluate implementation in real time, we will conduct prospective, linked qualitative IDIs with THRIVE SS staff depending on their involvement with the project. All THRIVE SS members who participate in the scheduled surveys will be asked to consent to be contacted for potential qualitative surveys as well. Based on Kvale’s estimate that 15 +/-5 individuals is sufficient to reach theoretical saturation,¹⁷² we expect this to be an adequate sample size; particularly for the small scale implementation assessment being conducted here. In addition to interviewing members at times of heavier involvement, we will also strive to interview different types of stakeholders (e.g., leadership, paid staff, and/or highly involved members who are involved in the ongoing *tele-B6* trial in any capacity) – although we will likely not be able to draw comparisons with this small sample size, we will still strive for representation of these different categories of individuals. We will create a semi-structured interview guide based on the CFIR, and follow procedures for remote and/or in person interviewing similar to those outlined in Aim 2. Interviews are expected to last 30-45 minutes, and stakeholders will also receive an additional \$25 electronic gift card for any qualitative interviews that they participate in. Some individuals may participate in more than one interview (for example, we expect that the computer specialist who updates the website will have heavy involvement necessitating multiple interviews).

Synthesis of Implementation Findings. Given that this assessment is still occurring within the context of a pilot trial, it will not completely predict “real-life” implementation experiences. However, these assessments will alert us to potential challenges (for example, if effort for the THRIVE SS computer specialist is higher than anticipated) that will need to be addressed prior to the next study. Additionally, documentation of the steps needed for implementation from the CBO side will inform development of an implementation manual – a guide that we will create based on the CFIR-guided assessment – that will be used in the follow-up trial.

7. Data Specimen Banking

Does not apply.

8. Sharing of Results with Participants

There are no individual results that would be shared with participants during the course of the study. In aggregate, 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.

9. Study Timelines

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: Adaptation with YAB					
Aim 1: Adaptation with THRIVE SS, EAP					
Aim 1: Facilitator Training					
Aim 2: Recruitment and enrollment of intervention arm					
Aim 2: Enrollment and follow-up of waitlist control arm					
Aim 2: Intervention and survey collection					
Aim 2: IDIs with participants					

[illegible]

Study Participants Recruitment and Participation Timeline. We would conservatively estimate that it will take 15.7 months to identify 204 eligible participants, of whom 60 would actually attend *tele-B6*. We will be continuously recruiting and enrolling for the study, beginning 2 months prior to planned commencement of the first baseline group. Surveys will be administered to participants at baseline, 2-, 4-, 6- month timepoints after the intervention as outlined above. Reminders to complete surveys will be sent via text message where needed.

10. Inclusion and Exclusion Criteria

Eligibility Criteria for Phases I and II will include, by self-report:

- (1)** Black race, inclusive of multiracial identities;
- (2)** male gender, inclusive of transgender men;
- (3)** self-identification as gay, bisexual, or another non-heterosexual orientation, and/or any history of consensual anal or oral sex with men;
- (4)** HIV-positive serostatus;
- (5)** age 18-29 years inclusive;
- (6)** residence in the Atlanta Metropolitan Statistical Area;
- (7)** available and interested to meet for two hours weekly over a six week period.

Eligibility will be assessed via a brief web-based screening survey administered either remotely or in person on a tablet.

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

For Phase III, eligibility criteria will include:

- (1) Paid staff or volunteer at THRIVE SS
- (2) Willing and able to complete surveys and interviews about implementation experience
- (3) Age 18 and above

11. Population

We are focusing exclusively on Atlanta-area YB-GBMSM 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.

External collaborators at University of Michigan will *not* enroll subjects or participate directly in protocol interventions. The protocol will take place exclusively at Emory University in Atlanta, GA, except for statistical analyses which will be completed virtually through a de-identified, secure database by [REDACTED] at the University of Michigan.

12. Vulnerable Populations

We will not be working with vulnerable populations.

13. Local Number of Participants

Phase I: 6 participants

Phase II: 60 participants

In Phase III: 15 participants

14. Recruitment Methods

Our multi-pronged outreach strategy will target YB-GBMSM at varying levels of engagement with HIV clinical and community organizations: **(1) Clinic-based recruitment:** The main clinical recruitment site will be the Grady Infectious Disease Program clinic (IDP) in downtown Atlanta. [REDACTED] have strong track records of both clinical practice and research based at the IDP.^{9,24,93,96,97} **(2) Research-based recruitment:** We will also recruit from existing research projects (our own and others – with support from the Emory Center for AIDS Research [CFAR] Clinical Core) in which participants have expressed interest in being contacted for future studies. **(3) CBO recruitment:** We will ask for referrals from THRIVE SS as well as other Atlanta CBOs that work with Black GBMSM living with HIV. We will post flyers in CBO offices and other community locations as recommended by our advisors. **(4) Online recruitment:** We will recruit on social networking apps and websites (e.g., Facebook, Jack'd) shown to be high-yield for recruitment of sexual minority men in research;¹³⁸ and post advertisements in online support groups and email listservs. We have found these strategies to be effective and acceptable in our prior work.^{28, 32, 139}

It will be important to make efforts to enhance retention and participation, while also not creating undue burden that could not be replicated during real-world implementation. Facilitators will utilize automated text message software (e.g., Twilio) to send periodic reminders and check-ins

(e.g., “time to log on to Zoom for B6!”; “Don’t forget to check out the case studies on www.thrivess.org”), as a low-intensity strategy for maintaining engagement. Text message reminders have been shown to enhance retention of Black GBMSM in prior intervention research.¹⁴¹

15. Withdrawal of Participants

Participants may withdraw from the study at any time. Once they have withdrawn, we will not collect any further data from these individuals.

16. Risk to Participants

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 YB-GBMSM living with HIV. 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.

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 on the study team, 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.

17. Potential Benefits to Participants

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 waitlist control arm will also receive the benefits of the intervention after a brief “waitlist” period.

18. Compensation to Participants

Phase I pilot participants will receive a \$25 electronic gift card after each of the six intervention sessions.

Phase II RCT participants will be asked to complete a brief session evaluation form at the end of each videoconference session, in which they will rate the content, facilitation and overall experience for the week; after each of these intervention sessions and evaluation forms they will receive a \$25 electronic gift card. Participants will also complete more in-depth surveys at varying intervals (0, 2, 4, 6 months for intervention and 0, 2, 4, 6, 8 for controls); upon completion of each, they will receive a \$25 electronic gift card. Participants who choose to additionally complete an in-depth interview will receive a \$25 electronic gift card upon completion. As such, participants can earn up to \$300 over the course of Phase II participation.

Phase III THRIVE SS staff will also be administered electronic surveys every 6 months through REDCap to assess implementation of tele-B6 in a community setting. At the completion of the survey, staff participants will receive a \$25 electronic gift card. We will also conduct prospective, linked qualitative IDIs with selected THRIVE SS staff, after which they will receive an additional \$25 electronic gift card.

19. Data Analysis, Management and Confidentiality

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.

Phase II: Randomized Control Trial

Statistical Analysis. Co-investigator [REDACTED] will lead all quantitative analyses. Our primary outcome is focused on descriptive analyses of the acceptability, feasibility and safety indices. We will assess intervention target outcomes (i.e., retention in care and viral suppression), hypothesized mediators (e.g., social capital, intersectional stigma), and background variables. These measures will be used to assess feasibility and acceptability (e.g., acceptability of items, length of time to complete surveys) of data collection.

Acceptability, feasibility, and safety: primary analyses. To evaluate *acceptability* of the intervention, quantitative analyses of the intervention data will be descriptive and concentrate on tabulating and summarizing post-session satisfaction survey measures. As described below, will also qualitatively analyze exit interviews conducted to assess acceptability and to identify any necessary modifications needed before a full trial. To evaluate *feasibility* of the intervention, we will monitor rates of recruitment and effort required (e.g. number of staff hours), number of screenings conducted and proportion eligible and agreed to enroll. Facilitators will complete a structured “intervention log” after each session, documenting level of fidelity to the curriculum. We will record number of rescheduled, cancelled and missed sessions and assessment visits to inform estimation of staffing needs and retention protocols for a subsequent full trial. We will also assess feasibility of verifying retention in care and viral load data by obtaining releases from participants to contact their provider and/or clinic by monitoring rates of verifiable EMR reports. To assess *safety*, we will tabulate and describe any reported adverse events that occurred during study participation.

Hypotheses and methods for exploratory analyses. Exploratory hypotheses will be evaluated as part of the feasibility assessment process. For example, we expect that intervention participants compared to those in the waitlist control condition will have H1: higher mean count of medical appointments attended, H2: higher probability of viral suppression, and H3: higher mean social capital scores. Means and proportions will be plotted from baseline to follow-ups to enable descriptive evaluation of overall patterns of change across time. As a data analysis feasibility check, we will use generalized linear mixed models (GLMM) for dichotomous variables (e.g., viral load) and semi-continuous count data (e.g., number of appointments attended) and linear mixed models (LMM) for continuous outcomes (e.g., social capital) to evaluate the proposed preliminary hypotheses. GLMMs fitted to count outcomes will use the best-fitting distribution from the Poisson family (e.g., Poisson, negative binomial; zero-inflated Poisson; zeroinflated negative binomial) with the log link function.¹⁶⁷ All mixed models will be estimated via maximum likelihood and will be fitted to ensure that all requisite information is available in the data to perform the types of analyses typically undertaken in a larger, formal RCT of the intervention's efficacy. Due to the modest sample size, significance testing will be de-emphasized. Similarly, although the modest sample size precludes investigating mediation formally, we will employ the LMM and GLMM approaches described as described above compare changes over time on the mediators listed in **Table 7**. We will follow an intent-to-treat design. Comparisons of characteristics of participants lost to follow-up to those who participate will be conducted to assess systematic patterns that could influence results.

Qualitative Analysis. Exit interviews will be digitally recorded, de-identified and transcribed verbatim. To support rigorous and reproducible qualitative analysis, [REDACTED] will lead team coding and analysis utilizing a pragmatic thematic analysis approach.¹⁶⁸ Analytic steps will include: **(1)** after each interview, interviewers will document field notes including emerging topic areas for subsequent exploration; **(2)** transcripts will be entered into MAXQDA qualitative

software for coding and analysis; **(3)** we will develop a preliminary codebook to include pre-determined deductive codes related to theoretical domains of interest (e.g., constructs from the conceptual model) and inductive codes that emerge from the data; **(4)** Analysts will code a subset of transcripts and compare coding, with differences discussed in team meetings until consensus is reached; **(5)** similarities and differences across transcripts will be examined, and codes and themes revised accordingly. We will cease developing new codes when no new themes are seen; **(6)** properties and dimensions of salient themes will be summarized and interpreted in detailed analytic memos (“thick descriptions”).

Phase III: Implementation

Data Analysis. Quantitative data analysis: Analyses of implementation measures will be descriptive, including summaries of survey responses to the scales measuring CFIR constructs. The small sample size will preclude further comparative analyses; however, these assessments will give a brief window into implementation and also afford us an opportunity to pilot our instruments ahead of a larger trial. Qualitative data analysis: will follow thematic analysis procedures described above in Phase II.

20. Provisions to Monitor the Data to Ensure the Safety of Participants

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 PI 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 that includes the date, a description of the event, duration, severity, actions taken to remedy the negative event (including professional referrals).

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.

Quality control/assurance. All data will be collected by trained staff members. [REDACTED] 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 [REDACTED] 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.

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 qualitative interviews (Phases II and III) and RCT participants could occur, as those YB-GBMSM 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 modified social capital scale, which has only had limited use in the YB-GBMSM population. Although our preliminary analyses have shown good reliability in other YB-GBMSM samples, it will be important to continue to examine the performance of this measure in this population. Finally, in terms of *analysis*, 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 YAB to ensure that our interpretation of our qualitative data is consistent with their general experiences.

21. Provisions to Protect the Privacy Interest of Participants

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 and consents will be kept in password protected files within HIPAA compliant shared drive folders only (e.g. Emory OneDrive, REDCap).

22. Economic Burden to Participants

The only potential cost of participation in the research study is the need for access to the internet to participate in the tele-B6 intervention; however, THRIVE SS has agreed to allow subjects to use computers with internet access to minimize this potential cost/barrier to participation.

23. Informed Consent

We will obtain electronic informed consent (including authorization for release of medical records for Phase II participants) using REDCap in one-on-one meetings conducted either via videoconference or in person prior to the first intervention session. This consent conversation will provide an opportunity to troubleshoot technical difficulties with the videoconference platform, orient participants to the THRIVE SS website, and complete the baseline REDCap survey. Consents will be signed and documented in REDCap with a copy sent to the participant after signing. Adequate time will be dedicated to the consent process to ensure full understanding

by participants and that all questions have been answered. Participants will receive contact information for study staff members and [REDACTED] for any questions or follow up concerns regarding the consent or study participation.

We are requesting a waiver of written consent for the IDI participants, 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)). Verbal consent will be obtained prior to each IDI.

All study staff who have direct contact with participants will be trained in the process of both verbal and written consent administration by [REDACTED]. 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.

24. Setting

The research will primarily take place in the virtual setting due to the nature of the study. In terms of recruitment, 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 YAB. 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. The CAB will be comprised of key stakeholders working with our target population in Atlanta.

25. Resources Available

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. 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, two of which are described below.

THRIVE SS is a nonprofit organization created for and by people living with HIV, with the overarching goal of providing a range of support services to men and women of color in the

Atlanta metro area. Most of the members are Black gay and bisexual men— their current estimated membership is 945 individuals. THRIVE SS has a long history of close collaboration with researchers in varying capacities— including assisting with recruitment and retention, serving on community advisory boards, and providing technical assistance and trainings to staff members where needed. THRIVE SS has served on advisory committees for [REDACTED] ongoing research in this area. Specifically for this protocol, THRIVE SS will serve to refer study participants and provide the physical space and internet (WiFi) to deliver our intervention to subjects who do not have another way to access tele-B6. Additionally, THRIVE SS staff and leadership will have the opportunity to respond to implementation surveys as study participants in Phase III of the protocol.

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