WITH U

Washington University School of Medicine

St. Louis, MO

Implementation of Evidence-Informed Behavioral Health Models to Improve HIV Health Outcomes for Black Men who have Sex with Men Initiative

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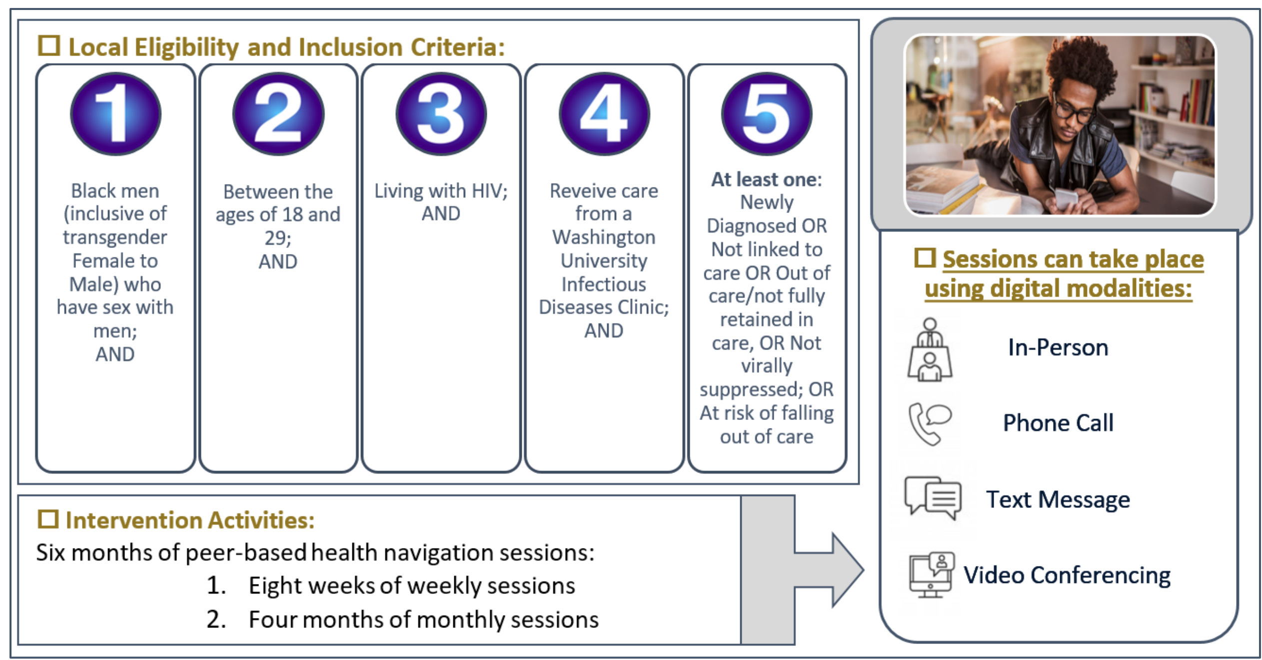
Executive Summary

Intervention Synopsis

WITH U paired peer health navigators (HNs) with Black youth and young adult men who have sex with men (YBMSM) with HIV to complete six months of intensive support via in-person, video chat, phone, and text conversations. WITH U, an adapted youth case management intervention, was implemented at infectious disease clinics associated with Project ARK (AIDS/HIV Resources and Knowledge), a Ryan White HIV/AIDS Program (RWHAP) Part D recipient of the Washington University School of Medicine (WUSM) in St. Louis, Missouri (more information about Project ARK and the population they serve is available below under *Where did WITH U Take Place?*). Implementation took place from October 2019 to July 2021, with a three-month disruption due to the coronavirus disease 2019 (COVID-19) public health emergency (PHE) from March 2020-June 2020.

The WITH U program provided education, support, and navigation assistance for Black men who have sex with men (BMSM), over the age of 18 and with HIV.[1] Program encounters were broken into eight weeks of weekly sessions followed by four months of monthly sessions and delivered with an intent-to-treat approach. The activities during those sessions were directed by the self-identified needs of the participant and/or self-directed goals set by the participant.



[1] Specifically, WITH U participants were newly diagnosed, not linked to care, out of care, at risk of falling out care (including due to behavioral health concerns), or not virally suppressed.

Though the COVID-19 public health emergency challenged intervention delivery, the WITH U program remained feasible, even when participants faced significant challenges around the social determinants of health which create social needs (e.g., hunger, unstable housing, poverty, experience of trauma, etc.). During qualitative interviews, participants reported that the services provided by the HNs were very important to them.

Rationale and Need

Many YBMSM with HIV have unique behavioral and social needs. YBMSM ages 18-29 experience higher HIV incidence rates and poorer health outcomes along the HIV care continuum compared to adults (over age 30) in St. Louis and across the United States.[i] In addition to dealing with HIV disease, many of these young people also experience significant adversity—trauma, poverty, racial discrimination, homophobia, and episodes of incarceration.[ii,iii,iv,v,vi,vii] The intersectionality and combined effects of mental health and substance use disorders, trauma, the social determinants of health (e.g., poverty, homelessness, unemployment), low health literacy, and racism are likely the cause of poor health outcomes among the YBMSM population enrolled in our intervention.[viii,ix,x] These health disparities highlighted a need to adapt current services and provide more direct, intensive services to those who may be more likely to not engage in HIV care and treatment.

To address these disparities and the needs of YBMSM, WITH U initiated a peer health navigation program that attended to behavioral health needs, health literacy, linkage to services, and psychosocial support through participant goal-setting activities. The peer health navigation services were integrated within Project ARK's existing youth-focused, multi-disciplinary team to provide intensive support to YBMSM along the HIV care continuum. While Project ARK previously had peer educators that work with participants along the HIV care continuum, the WITH U program enhanced the structure and expanded the services provided by the peers. The increased intensity of WITH U included additional formal meetings with the HN, more focused action plans, and a closer monitoring of progress than general peer programs. WITH U created formal criteria for referral into the program, delineated the time-period that participants spend in peer health navigation services, and assessed participants' progress within the program. By adding universal screening for peer health navigation services based on specific inclusion criteria (lost to care, new to care, not virally suppressed, or at risk of falling out of care), the WITH U program directly assisted those participants with the highest need for support. Additionally, rigorous assessment within a specified timeframe allowed meetings and activities to be customized and provided an increased level of program evaluation.

Intervention Description

WITH U was a six-month, peer-based, health navigation program consisting of 12 one-on-one sessions between a HN and a participant. Health navigation services supplemented standard services provided by RWHAP-funded medical case managers (MCMs) within three infectious

diseases clinics at WUSM. HN sessions took place in-person, or by phone call, text message, in app messaging, and/or video conferencing. The activities during these sessions were focused on health education, care navigation, and support, as directed by the participant's needs and goals. Additionally, the WITH U program collaborated with the behavioral health team, known as the "Mental Wellness" program at WUSM, for active referrals and follow-up to participant mental health needs.

WITH U Model at-a-Glance	
Step 1	**Participant identified as eligible for WITH U program** BMSM participants between 18-29, who are newly diagnosed, lost to care, not virally suppressed, or at risk of falling out of care are referred into the WITH U project.
Step 2	**Enrollment staff conducts a comprehensive assessment** Assessment tools include the PHQ-8, CRAFFT, PCL-C, and GAD-7 (see *Implementation* section).
Step 3	**Enrollment staff submits referrals to team members** • Enrollment staff member makes a referral to a HN. • Enrollment staff member completes a **mental wellness referral** if scores on screening tools meet threshold.
Step 4	**HN holds first session with participant to introduce the program and build rapport** • HN explains their role and their expectations of the participant. • HN assesses the best time to disclose their HIV status to the participant.
Step 5	**Participant and HN establish individualized goals**
Step 6	**HN conducts weekly and monthly health navigation sessions** • 12 sessions: 8 weekly for two months, followed by 4 monthly sessions. • Sessions focus on health education, support, care navigation, and reinforce mental wellness referrals. • Ad hoc communication via text messaging, drop-in visits, and phone calls. • Work collaboratively with MCM to provide needed referrals and support.
Step 7	**Behavioral health specialist provides mental wellness services** • Reaches out to referred participants to engage in services. • Communication includes phone calls and telehealth visits. • Conducts sessions with participants at agreed upon times.
Step 8	**Multi-disciplinary team conducts monthly case conferencing**

Intervention Summary

For successful start-up of a peer health navigation program like WITH U, the Washington University team identified the following activities as crucial during pre-implementation:

- Assess organizational commitment and capacity for integrating and supervising peer HNs
- Establish organization-wide understanding of the roles and collaborative relationships of members of multi-disciplinary teams
- Thoroughly train staff
- Develop a system of referral to meet participants' identified psychosocial needs

Elements essential to the replication of WITH U include:

- Using screening tools that provide information on factors that impact a participant's ability to achieve improved clinical outcomes
- Deliver health navigation functions, which include education, support, and navigation
- Establish a system for goal setting and analyzing goal attainment
- Regularly check-in on mental wellness readiness and/or utilization
- Create a routine time and space to bring all members of the multi-disciplinary team together to focus on participant needs
- Increase efforts to maintain an open channel for communication between the HN and participant

Once enrolled in health navigation, participants participated in twelve health navigation sessions completed in-person or virtually over six months, delivered in an intent-to-treat model. Sessions focused on education, support, navigation, goal setting, and linkage to mental health (when indicated).

Key roles needed for delivery of WITH U include:

- Health Navigators
- Health Navigator Supervision
- Mental Health Provider(s)
- Support provider for staff professional and emotional support

Evaluation of the WITH U intervention revealed the following outcomes:

- Participants in WITH U reported a high satisfaction with the intervention
- Attending a greater number of sessions was associated with being virally suppressed
- HN assistance with basic needs was critical to participants
- HNs provide critical emotional support in the absence of mental wellness engagement
- In the face of significant adverse life circumstances and substantial need, most participants attended at least half of their intended sessions

More in-depth discussion of the findings and considerations for implementing health navigation are included below.

Introduction

This Implementation Manual provides guidance on how to adapt and implement WUSM's **WITH U** program to facilitate future replication. This Manual describes the selected model of care (MOC) with adaptations, pre-implementation activities, local evaluation, intervention components, implementation experiences, and intervention outputs and outcomes. This Manual also shares lessons learned and best practices to support successful replication of intervention components.

This Manual provides a broad, concise overview of WITH U to a diverse audience of clinical leadership, HIV service providers, and other stakeholders interested in identifying and implementing new, innovative strategies for improving care for BMSM with HIV and other populations in their communities. More detailed information for future replicators can be found in the Implementation Toolkit.

About this SPNS Initiative

HRSA's RWHAP provides a comprehensive system of HIV primary medical care, essential support services, and medications for low-income people with HIV who are uninsured and underserved. The RWHAP funds grants to states, cities/counties, and local community-based organizations to provide care and treatment services to people with HIV (PLWH) to improve health outcomes and reduce HIV transmission among hard-to-reach populations.

The intervention outlined in this Implementation Manual was part of the *Implementation of Evidence-Informed Behavioral Health Models to Improve HIV Health Outcomes for Black Men who have Sex with Men* Initiative (otherwise known as the "BMSM Initiative"). This Ryan White HIV/AIDS Program (RWHAP) Special Projects of National Significance (SPNS) Initiative was funded by the HRSA HIV/AIDS Bureau (HAB), and the intervention was conducted and evaluated within a RWHAP-funded site. The WITH U intervention was implemented by WUSM, a RWHAP Parts C, D, and F Recipient and a RWHAP Part A and Part B Sub-Recipient based in St. Louis, Missouri.

The RWHAP SPNS Program is funded under Part F of the Ryan White HIV/AIDS Treatment Extension Act of 2009, and administered through the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Division of Policy and Data (DPD). The RWHAP SPNS supports the development of innovative models of HIV care and treatment to quickly respond to emerging needs of RWHAP. Through its demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health related outcomes of treatment models while promoting the dissemination and replication of successful interventions.
The RWAHP SPNS advances knowledge and skills in the delivery of health care, support services, and data integration to underserved populations with HIV.

Specifically, the three-year BMSM Initiative funded eight demonstration sites (or recipients) to adapt, implement, and evaluate four evidence-informed behavioral health interventions and/or models of care to engage, link, and retain BMSM with HIV in medical care and supportive services. The interventions focused on strategies to integrate behavioral health services with HIV clinical care to specifically address the needs of BMSM with HIV and improve their health outcomes. Each recipient adapted one of four MOCs to create an innovative, integrated intervention to serve BMSM with HIV in their respective community.

The Need

Many YBMSM with HIV have unique behavioral and social needs. In addition to dealing with HIV disease, many of these young people also experience significant adversity—trauma experienced because of crime, violence and discrimination, concentrated poverty, racial discrimination, homophobia, and episodes of incarceration.[ii,iii,iv,v,vi,vii] The intersectionality and combined effects of mental health and substance use disorders, trauma, the social determinants of health (e.g., poverty, housing instability, unemployment), and racism may make the population of YBMSM in our intervention particularly vulnerable to poor health outcomes.[viii,ix,x] Additionally, the 2014 police shooting death of teenager Mike Brown in Ferguson (St. Louis County) and the considerable unrest that occurred, and then again in the aftermath of the 2020 death of George Floyd in Minneapolis, inflicted more traumatic experiences for many YBMSM in St. Louis.[xi] Although community service organizations, schools, businesses, and academic centers including Washington University mobilized to respond to the racial prejudice, marginalization, and community policing issues that were identified, it will take years to improve the impact these experiences have had on the region's young people.[xi]

Intervention Overview

The Basics

What is WITH U?

WITH U, a peer-based, health navigation intervention, was adapted from a clinic-based, youth-focused case management program developed and evaluated by the Los Angeles County Department of Public Health.

Original MOC

As noted above, each RWHAP SPNS recipient for this Initiative adapted and implemented one of four evidence-informed MOCs expected to improve linkage to care, engagement in care, retention in care, and HIV health outcomes, and address the comprehensive needs of BMSM with HIV. All of the MOCs were originally developed to improve HIV care and treatment and/or HIV health outcomes for youth and/or adult men of color. Washington University's Project ARK adapted a **youth-focused case management** intervention.[xii] Key components of the original MOC included two Bachelors-level case managers (CM); clinic- and venue-based outreach; a 24-month intervention; and provision of psychosocial case management services. The following

table briefly describes the implementation process of the youth-focused case management model.

Original Model at-a-Glance	
Youth-Focused Case Management	
Step 1	Participant referred to **peer case manager (CM)**
Step 2	CM conducts a **comprehensive assessment**
Step 3	CM develops an **individualized treatment plan**
Step 4	CM **provides referrals** Refer to needed services, including social support and behavioral health
Step 5	CM meets with participant to **assess progress in their treatment plan** • Scheduled visits are weekly for two months and monthly for 22 additional months. • Ad hoc communication via text messaging, drop-in visits, and phone calls.

Adaptations

In considering the successes and challenges described in the full final report on the original youth-focused case management MOC from the Los Angeles County Department of Public Health, the WUSM team chose to change components of the MOC, based on recommendations of the original researchers and to accommodate the capacity of local program staff. These included:

- **Expanding the age of inclusion** from 18-24 year old MSM of color to 18-29.
- **Shortening the duration of the intervention** to two months of intensive weekly intervention and four months of monthly intervention for a total of six months of intervention.
- **Utilizing peer staff as HNs** to direct the services provided throughout the intervention in lieu of traditional CMs.

- **Focusing on identifying and addressing behavioral health barriers** and improving self-management.
- **Integrating HNs into an existing multi-disciplinary team** that consists of youth/young adult-specific MCMs, mental wellness providers, and medical providers.
- **Conducting peer health navigation appointments using communication methods other than in-person meetings** (i.e., telephone calls, text messaging, and video conferencing).

The following table describes the WITH U program as modeled by WUSM. Readers can review this step-by-step overview for replication.

Adapted Model at-a-Glance	
WITH U	
Step 1	**Participant identified as eligible for WITH U program** BMSM participants between 18-29, who are newly diagnosed, lost to care, not virally suppressed, or at risk of falling out of care are referred into the WITH U project.
Step 2	**Enrollment staff conducts a comprehensive assessment** Assessment tools include the PHQ-8, CRAFFT, PCL-C, and GAD-7 (See *Implementation* section).
Step 3	**Enrollment staff submits referrals to team members** • Enrollment staff member makes a referral to a HN. • Enrollment staff member completes a **mental wellness referral** if scores on screening tools meet threshold.
Step 4	**HN holds first session with participant to introduce the program and build rapport** • HN explains their role and their expectations of the participant. • HN assesses the best time to disclose their HIV status to the participant.
Step 5	**Participant and HN establish individualized goals**
Step 6	**HN conducts weekly and monthly health navigation sessions** • 12 sessions: 8 weekly for two months, followed by 4 monthly sessions. • Sessions focus on health education, support, care navigation, and reinforce mental wellness referrals. • Ad hoc communication via text messaging, drop-in visits, and phone calls. • Work collaboratively with MCM to provide needed referrals and support
Step 7	**Behavioral health specialist provides mental wellness services** • Reaches out to referred participants to engage in services. • Communication includes phone calls and telehealth visits. • Conducts sessions with participants at agreed upon times.
Step 8	**Multi-disciplinary team conducts monthly case conferencing**

Who was the WITH U Target Population?

The WITH U program was designed for:

Black men (inclusive of transgender Female to Male) who have sex with men; AND	Between the ages of 18 and 29; AND	with HIV; AND	Reveive care from a Washington University Infectious Diseases Clinic; AND	**At least one:** Newly Diagnosed,[a] OR Not linked to care,[b] OR Out of care/not fully retained in care,[c] OR Not virally suppressed,[d] OR At risk of falling out of care[e]

a) Newly diagnosed: Tested HIV positive for the first time within the last 12 months.
b) Not linked to care: Aware of their HIV infection status, but have never been engaged in HIV care (i.e., never had an HIV medical visit after being diagnosed with HIV).
c) Out of care/not fully retained in care: Diagnosed with HIV more than 12 months ago, but does not have two HIV medical appointments that are AT LEAST 90 days apart. ***Note:*** *HIV medical visits are defined as seeing an HIV medical provider or completing a CD4 and/or viral load test.*
d) Not virally suppressed: Having a viral load equal to or greater than 200 copies/mL at the last lab test.
e) At risk of falling out of care:
    - Substance use (more than five drinks in a day or any recreational substance use) in the past year
    - History of having a sexual transmitted infection in the past year
    - Housing instability in the past year
    - Joblessness of more than three months in the past year
    - Having a positive score on the PHQ-2
    - Having been released from incarceration within the past year
    - Having a negative experience with an HIV provider

Where did WITH U Take Place?

The WITH U program was implemented at infectious disease clinics associated with Project ARK in St. Louis, Missouri. Project ARK, a program of the WUSM, has served as the St. Louis region's only RWHAP Part D recipient since 1995. Project ARK is the largest provider of care and prevention services to youth (ages 13-24) at risk for and living with HIV in the St. Louis region. Project ARK provides a comprehensive continuum of HIV care and prevention services including HIV testing, linkage to care, medical and behavioral health services, and medical case management and serves the vast majority of PLWH in care within the region. In 2020, Project ARK provided services to 1,153 clients living with HIV, including 223 youth with HIV, of which 118 (53 percent) are Black/African American that self-identified as MSM.

Why WITH U?

Recognizing the particular needs of the YBMSM population and the challenges that impact their care, WITH U applied the principle of social proof, namely that in uncertain circumstances, having someone who is most like you helping you make decisions about your health may be preferred.[xiii] While Project ARK utilizes peer educators with clients to support the HIV care continuum, the WITH U intervention improved the structure and expanded the use of peer services. In particular, WITH U expanded the role of peer educators in intensity, scope of services offered, and specificity to a population. The increased intensity of WITH U included additional formal meetings between the HN and participant, more focused action plans, formalized case conferencing, and closer assessment of progress. In addition, the WITH U HNs drew from multiple evidence-informed program components and customized activities to optimize health-related behaviors in participants. Prior to WITH U, no formal criteria or timeframe for referral into peer programming existed and participant's progress within the existing program was not formally assessed. By adding universal screening for health navigation services based on specific inclusion criteria (i.e., lost to care, new to care, or at risk of falling out of care) and utilizing opt-out recruitment, WITH U assisted those with the greatest need for support. In addition, consistent with the Peers for Progress model, [xiv] WITH U HNs focused on support, education on managing a chronic illness, and system navigation—namely how to link and engage with the needed resources, whether that be mental health services, housing, food, transportation, or other psychosocial needs. Rigorous assessment within a specified timeframe allowed customized meetings and activities and provided an increased level of program evaluation. Through exploratory and qualitative analysis, we also hoped to better identify the challenges of building the bridge between screening and linkage to mental health services in the moment and for future efforts.

Pre-Implementation Activities

Organizational Commitment and Capacity

Clinical and administrative supports are critical to the successful integration of HNs within an HIV care program. Utilizing peer community workers is more than simply hiring people who are representative of the community you serve. It requires a programmatic commitment to integrate peers into every aspect of services, to amplify their voices, and to adequately train and fully support peer staff as they may experience re-traumatization and secondary stress.

Navigator Note… on employing peer HNs:
Your organization needs to meet the challenge of treating peers and community health workers as equal members of the team. Provide the same benefits, including opportunities for promotion and education/tuition reimbursement, as other social services staff. Not having a structure that allows for professional advancement will cause your organization to lose people and their experience – and will mean having to hire and train new employees! Lack of opportunities for growth is directly connected to burnout.

The WUSM team identified the following activities as crucial to the successful start-up of a peer-based health navigation program like WITH U. An organization should allow ample time to consider these steps, as some steps may require significant time, such as hiring and onboarding peer staff, acquiring necessary equipment, and achieving staff buy-in.

Resource Assessment Checklist

The WITH U program was specifically tailored for implementation in RWHAP-funded clinical care centers where peer-based health navigation services are available as part of a multi-disciplinary team. The structure of services at RWHAP health programs/centers allows for both the clinical and social support services of the program to be optimized. However, WITH U can be implemented at any HIV care center or primary healthcare site with the right components in place or the ability to develop these necessary components. Questions to consider include:

- ❑ Does your organization provide *HIV primary care services* or have a formal relationship with an organization that does?
- ❑ Does your organization have the capacity to have or hire a lead staff person to champion the program?
- ❑ Does your organization have the capacity for on-going clinical supervision and management of secondary stress for peer health workers?
- ❑ Does your organization provide *behavioral health services* or have a formal relationship with an organization that does?
- ❑ Is there a system in place for participants to be referred for mental wellness services based on self-referral or referral due to positive scores on selected screening tools?
- ❑ If a participant identifies a need, are there available community resources to meet that need?
- ❑ Are the financial resources available for acquiring communication technology? This may include mobile phones for staff and a contract with a technology platform.
- ❑ Has your organization established policies around protecting the privacy of patient information when using mobile technology?*
- ❑ Can staff be adequately trained to respond to needs as well as use of technology and privacy/usage policies? *
- ❑ Does your organization have a crisis intervention plan that can be applied during the intervention?

*See *Authorization for Unencrypted Electronic Communication*, *Standard Operating Procedure Medical Case Management Guidelines*, and *Privacy Safety Assessment* in the Implementation Toolkit.

Navigator Note… on program supervision:
The supervisor of the health navigation program should reflect the values of the program as well as have a commitment to the population being served. If the population is youth, the supervisor should be someone who has extensive experience working with youth and [has] a passion and desire to promote change that can yield positive outcomes for the population. It's important for the supervisor to be someone who is aware of the unique barriers faced by the population and the underlying issues that make this particular population especially vulnerable for HIV as well as negative health outcomes. They should be someone who understands systemic racism and how it plagues the community in terms of health care, housing, equitable pay on jobs, etc. The supervisor should be someone with an open door policy and who is willing to assist the health navigators as well as advocate on their behalf when issues arise.

Cost

Estimated key costs related to implementation of this peer-based health navigation intervention are in the table below. A summary of primary costs include:

1. HN positions
2. Support for critical roles in the program:
   a. Program oversight and clinical supervision to HNs
   b. HN training
   c. Emotional support and professional debriefing for HNs
   d. Mental health provider
3. Smartphones for staff and/or participants to remain in contact
4. Costs for staff cellular phone service

WITH U COSTING ESTIMATE

Item (based on two HNs)	Estimated Annual Cost
Cell phone costs ($750.00 ea. with 2-year contract)	$1,500
Cell phone line/data cost	$1,560
Health Navigators (2 x 1.0 FTE)	$104,000
Health Navigator Supervision (.25 FTE)	$23,500
Mental Health Provider (.25 FTE)	$20,000
Consultant ($2,000) and Training ($6,000)	$8,000
Total	**$158,560**

Internal Partnerships

Project ARK's team included behavioral health professionals, treatment adherence experts, MCMs, medical providers, and a multitude of other resources. HNs were integrated members of the participant's care team. Open and continuous communication during case conferences and within a unified documentation system allowed for better tracking of participant progress. The table below describes how Project ARK HNs coordinated with existing staff roles.

Staff Member	Role	HN Collaborative Activities with Staff Member
MCM	Facilitate clients' access to financial support and services from federal, state, and local programs including Medicaid, social security, and other RWHAP-funded services to meet clients' health and mental wellness needs. MCMs arrange access to services including assistance with insurance, medical care, housing, food, transportation, medications, translation services, and other services as needed to support clients. MCMs coordinate with HIV medical staff to develop care plans and other care coordination meetings.	- Develop Treatment Plan - Identify needed referrals - Facilitate referral access - Address barriers to care - Initiate contact with lost participants - Encourage engagement with care team
Mental Wellness Specialist	Provide individual, couple/family, and crisis intervention counseling. Coordinate clients' access to psychiatry and substance abuse services as needed.	- Introduce mental wellness services/staff - Assess and promote readiness for mental wellness resources - Reinforce engagement
Community Nurse	Provide intensive care coordination including home visits, reminders and attendance of medical visits, HIV and adherence education, and use of motivational interviewing to promote HIV disease self-management.	- Consult for in-depth adherence counseling - Educate on medical aspects of HIV and other medical care and treatment
HIV Medical Provider	Offer one-stop medical homes for clients to receive HIV primary medical care by a board-certified physician.	- Foster engagement in high quality HIV care and treatment - Facilitate adherence to ART - Educate on medical management of chronic illness

Navigator Note… on internal collaborations:
Ensure that the multidisciplinary team understands the mission and values of the program in an effort to solidify the role of health navigator within the multidisciplinary team. You may want to set up dates and times for the health navigators to meet each person on the team face-to-face,

similar to an in-service, so that questions can be asked and answered by clinical and social service staff concerning the role of health navigator.

Training

Comprehensive and on-going HN training was critical for successful administration of the WITH U program. HNs were trained and supervised by a masters-level licensed clinical social worker. The job description for the HN position can be found in the Implementation Toolkit. The table below describes the recommended training modules that a peer HN completes to successfully carry out this MOC and the HN position in our program (see *Health Navigator Training Protocol* in the Implementation Toolkit for a comprehensive list of trainings completed by WITH U HNs).

SPNS BMSM: Health Navigator Training Modules
Washington University School of Medicine

Training Module	Topics Covered
Peer Navigation Job-Specific Training	Medication Adherence/Treatment, Social Determinants of Health, Setting Boundaries, Resolving Conflict, Burnout, Self-Care, Trauma-Informed Care, Building Blocks to Peer Success
HIV-Specific Training	Introduction to HIV, HIV Lifecycle, Prevention with Positives, Understanding U=U, HIV and Aging, HIV and Mental Health
Human Research Training	CITI Training, HIPAA/Privacy, Good Clinical Practice
Job/MOC Function Training	Motivational Interviewing, Mental Health First Aid, Administering Screening Tools, Health Literacy, Goal Setting, Case Conferencing
Agency-Specific Training	Agency Orientation, Code of Conduct, Safety on the Job, Ethics, Team Dynamics, Documentation Systems, Quality Improvement 101
Social and Racial Justice Training	Cultural Competency, Working Towards Racial Equity, Anti-Racism

Navigator Note… on training:
It is beneficial to have trainings conducted independently, by outside agencies that may not have an interest or affiliation with the organization or program.

Call out: HNs need strong supervision and support!
The HNs that delivered the WITH U intervention consistently highlighted the need for people who work in these positions, especially those who are members of the target population themselves, to receive regular supervision and other supportive services. Support for HNs can included, but is not limited to:

- Regular (weekly) one-on-one sessions with a support provider or therapist to process the work
- Monthly group sessions with other front-line providers (without supervisors present) to debrief and support each other
- Trainings on avoiding burnout and compassion fatigue

- Supervisor support for utilizing time-off, help with committing to personal boundaries, and flexibility for attending to life needs/circumstances

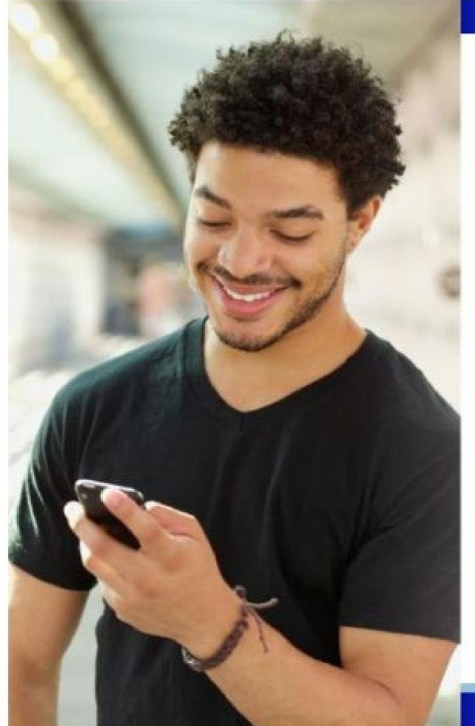
Develop a Plan for Participant Recruitment/Engagement

WITH U enrollment staff relied on an in-reach strategy to identify candidates for the intervention. Using the integrated medical record system, staff pre-screened clients who had clinic appointments each week. Enrollment staff then approached the potential participants during medical visits. Additionally, to aid with recruitment, the WITH U team collaborated with linkage to care, lost to care, youth, and young adult MCMs, as well as with a quality improvement program for clients who were persistently viremic. WITH U staff educated all MCMs about the program to provide them the opportunity to identify people who were eligible on their caseload and refer them. Lastly, medical providers were able to provide direct referrals into the program. Generally, recruitment took place in-person at the clinic, where enrollment staff were available to discuss the program and offer same-day or remote enrollment.

In addition, in collaboration with community advisors, the WITH U team created materials to promote participant engagement (see below). These advisors included Tuesday Night Crew (TNC) (a weekly MPowerment initiative for gay and bisexual black men) participants, the TNC leadership board, and volunteers from a previous SPNS Initiative that served a similar population. They provided input on project details. For example, the advisory groups were engaged to offer feedback on the project branding, including the name and logo, and feasibility of the intensive peer navigation services.

Recruitment Brochure

(Front)



RIGHT THERE WITH U…

That's Where We'd Like to Be

Participate in a research study* to determine if working with a health navigator for six months will improve your healthcare.

FOR IRB USE ONLY
IRB ID #: 201905070
APPROVAL DATE: 10/09/19
RELEASED DATE: 10/09/19
EXPIRATION DATE: N/A

(Back)

WHO IS THIS FOR?

⇒ Men (inclusive of transgender men and gender non-binary persons born male)

⇒ Who have had sex with men in the last five years

⇒ Between the ages of 18 and 29

⇒ Who are receiving care from a Washington University Infectious Disease Clinic

WHAT WILL HAPPEN?

⇒ A Health Navigator will work with you intensively for 6 months

⇒ Have access to regular, one-on-one, Health Navigation sessions (which can take place in person or digitally)

⇒ Receive up to $100 in Walmart or Target gift cards for participation

WHAT WILL YOU DO?

⇒ Complete one in-person enrollment session and survey

⇒ Allow access to your healthcare information during study

⇒ Attend Health Navigation sessions, weekly for 2 months, then monthly for 4 months.

⇒ Participate in evaluation sessions at 2 months, 6 months, and 12 months to complete a 45-60 minute survey

SIGN UP?

Contact Jeff Glotfelty at (314) 273-9069
Or
Stacey Slovacek at (314) 565-2865

*Katie Plax, M.D., Division Director of Adolescent Medicine, is conducting this study.

Promoting WITH U to Internal Partners

The WITH U team met with program leadership at each clinical site to plan for recruitment. Planning activities included:

- Identification of dedicated spaces to conduct recruitment and enrollment activities
- Discussion of clinic flow processes
- Integration of recruitment activities in the clinic
- Education of all staff about the project.

The WITH U team educated medical providers on the WITH U project and the basic eligibility criteria. Promotional items were developed to educate clinical and social services staff about the program. One-pagers were distributed at departmental meetings and posters were hung in office spaces as a reference (see *Clinician Information Flyer* in the Implementation Toolkit).

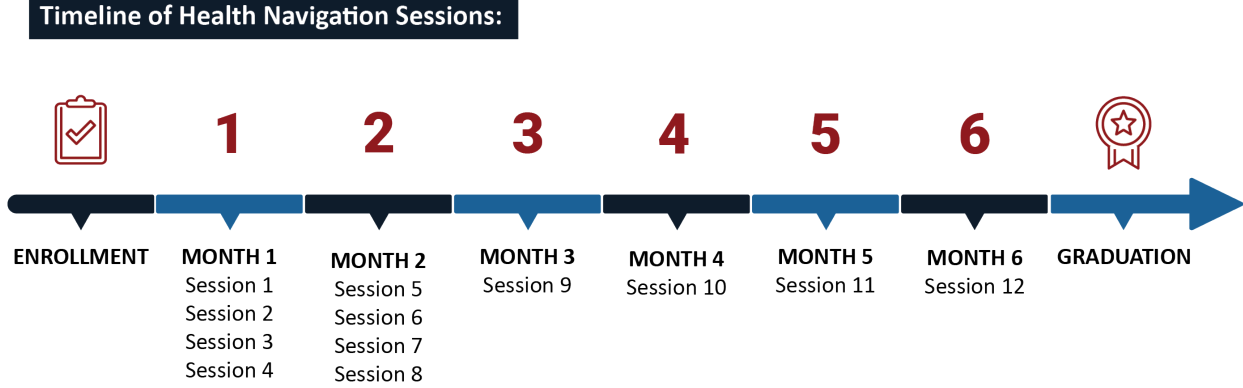
Throughout the programmatic period, the WITH U team updated the multi-disciplinary staff of the status of WITH U program. HNs communicated with providers and social services staff about program activities and participant specifics by documenting sessions in the participant's electronic health record (EHR).

Navigator Note… on team communication:
Utilizing EPIC [the EHR] is a game-changer in reference to connecting social service team members to the clinical staff. When issues arise, they are addressed more quickly and team members are more likely to be informed about what is going on with each client due to the use of EPIC as a way to communicate as well as share medical information and new barriers or challenges faced by clients.

Implementation

WITH U Sessions Overview

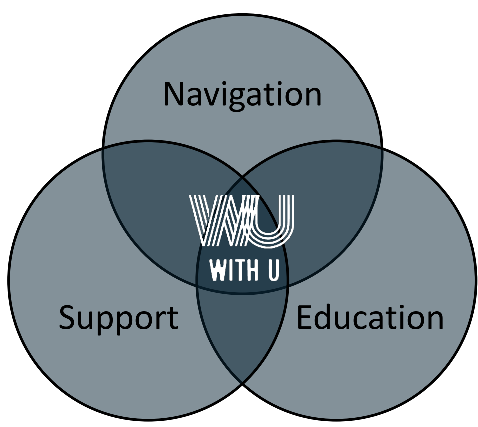
The WITH U team worked to define the role of a HN and operationalize the function of the WITH U program within our RWHAP Part C/D programs. The program focused on identifying behavioral health factors that impact a participant's ability to achieve improved clinical outcomes and establishing a system for goal setting and analyzing goal attainment. WITH U's six-month, peer-based, health navigation program centered around 12 one-on-one sessions between a HN and a participant (conducted in-person and via phone call, text message, in-app messaging, or video conferencing).



The activities during these sessions were directed by the participant-identified needs and focused on education, navigation, and support.

- Screening Tools: The screening tools selected included an evaluation of social determinants of health;[xv] standard mental health screeners: the Patient Health Questionnaire-8 (PHQ-8)[xvi], the 2-item PTSD Checklist - Civilian Version (PCL-C)[xvii], and the Generalized Anxiety Disorder Screener (GAD-7)[xviii]; and the substance-related risk assessment tool, the CRAFFT[xix]. These assessment tools were used in conjunction with clinical eligibility screening data to establish a plan of action between the HN and the participant.

- Role of HN/Supporting Participant Goals: Best practices, published by Peers for Progress (http://peersforprogress.org), suggest peer program standardization based upon the "functional components of peer support". In collaboration with the HNs and resources from the Peers for Progress program, the WUSM team defined the core functional components of peers within our program and adapted the operational definitions from the Peers for Progress program.[xx] We determined these functions to be:
  - Education - Assistance in applying disease management or prevention plans in daily life (e.g., goal setting, skill building, practice and rehearsal of behaviors, trouble-shooting, and problem solving);
  - Support - Emotional and social support (e.g., encouragement in skills use, dealing with stress, and being available to talk with people troubled by negative emotions);
  - Navigation/Linkage - Liaison to clinical care, patient activation to communicate and assert themselves to obtain regular and quality care, linkage to behavioral health, utilities, etc.[xxi]



Enrolled Participants

WITH U was developed for YBMSM to address the underlying causes of disparities in the HIV care continuum unique to that population. During WITH U's recruitment period (October 2019 – December 2020), staff enrolled 65 youth from the three Washington University HIV clinics.

The 65 YBMSM WITH U participants were an average age of 25-26 years (M=25.49, SD=2.51). Approximately one quarter of participants scored at or above the clinical cutoff for depression or anxiety symptoms, and over 40 percent reported being bothered by past traumatic stressors in the last month. More than half of participants reported either worrying about or experiencing food instability in the last three months, over a third were concerned about losing their housing, and a quarter were unable to get their utilities paid when needed.

Table 1. Intervention participant demographics and risk factors at enrollment (n=65)

Demographics	N (%)
Race (check all that apply)	
Black	65 (100)
White	3 (4.6)
American Indian/Alaska Native	1 (1.5)
Asian	1 (1.5)
Some Other Race	1 (1.5)
Ethnicity	
Not Hispanic, Latino, or Spanish origin	60 (92.3)
Unsure	3 (4.6)
Gender	
Man	64 (98.5)
Genderqueer/Gender non-conforming	1 (1.5)
Education Level	
Finished grade school	2 (3.1)
Some high school	1 (1.5)
High school diploma or GED	16 (24.6)

Demographics	N (%)
Some college, professional, vocational, or trade school	18 (27.7)
Graduate college	3 (4.6)
More than college	1 (1.5)
Other	1 (1.5)
Current Employment Status	
Employed at a company	38 (58.5)
Self-employed	4 (6.2)
Unemployed	18 (27.7)
Unable to work/disabled	1 (1.5)
Student	2 (3.1)
Other	2 (3.1)
Income Level-Last 12 months	
$5,000 or less	23 (35.4)
$5,001 to $10,000	9 (13.8)
$10,001 to $20,000	12 (18.5)
$20,001 to $40,000	12 (18.5)
Unsure	9 (13.8)
*Age**	25.48 (2.51)
Psychosocial Risk Factors	
Depression (PHQ-8 ≥ 10; last 2 weeks)	17 (26.2)
Anxiety (GAD-7 ≥ 10; last 2 weeks)	17 (26.2)
Bothered by re-experiencing past stress (moderately or higher)	30 (46.2)
Bothered by feeling upset when remembering past stress (moderately or higher)	28 (43.1)
Possible substance use problems (CRAFFT ≥ 2)	49 (75.4)
Used marijuana or other recreational drug in last 12 months	45 (69.2)
Engaged in binge drinking in last 12 months	45 (69.2)
Felt like alcohol or drugs are causing problems in life	12 (18.5)
Worried about food instability in last 3 months	39 (60.0)
Experienced food instability in last 3 months	37 (56.9)
Unable to get utilities when needed in last 3 months	17 (26.2)
Worried about losing housing	24 (36.9)
Felt physically and emotionally unsafe in current housing	4 (6.2)
Physically abused/attacked in past 3 months	6 (9.2)
Humiliated or emotionally abused in last 3 months	17 (26.2)
Released from jail or prison in last 12 months	5 (7.7)

*M (SD)

	Participants Recruited	**65**
	Average Age	**25.5**
	Worried about Food Insecurity	**60%**
	Unemployed	**27.7%**
	Reported Housing Instability	**36.9%**
	Reported Being Bothered by Past Traumatic Stressors in the Last Month	**46.2%**

Intent to Treat:

Once a participant attended their first HN session, which had to be completed within the first month after enrollment into the study, the participant would not be withdrawn from the Intent-to-Treat (ITT) intervention unless they moved out of the service area, passed away, or requested to be removed from the study. The participant, regardless of the number of sessions completed after the first session, remained in the intervention for six months. If at any point the participant requested to be withdrawn from the intervention, the participant would be completely removed from the study.

Core Components

WITH U defined the role of a HN and operationalized the function of HNs within a multi-disciplinary system. Elements essential to the replication of WITH U include:

1) Screening

Use screening tools that provide information on factors that impact a participant's ability to achieve improved clinical outcomes. As described above, the screening tools employed included an evaluation of social determinants of health; standard mental health screeners: the PHQ-8, the 2-item PCL-C, and the GAD-7; and the CRAFFT substance-related risk assessment tool. These assessment tools were used in conjunction with clinical eligibility screening data to establish a plan of action between the HN and the participant.

2) Education, Support, and Navigation

Deliver health navigation functions, which include education, support, and navigation. The WITH U team worked collaboratively with Project ARK's existing peer health coach team to identify health navigation best practices and define the core functions of HNs. Adopting the operational definitions from the Peers for Progress program,[xxii] these teams defined the core functions as:

- Education - Assistance in applying disease management or prevention plans in daily life (e.g., goal setting, skill building, practice and rehearsal of behaviors, trouble-shooting, and problem solving);
- Support - Emotional and social support (e.g., encouragement in use of skills, dealing with stress, and simply being available to talk with people troubled by negative emotions);
- Navigation/Linkage - Liaison to clinical care, patient activation to communicate and assert themselves to obtain regular and quality care, linkage to behavioral health, and linkage in terms of referrals to mitigate social determinants of health (e.g., food, housing, utilities, etc.).

3) Assist Participants with Goals

Establish a system for goal setting and analyzing goal attainment. Collaborating with the participant on goal setting and developing a structured plan for reaching goals was a central function of health navigation sessions. The goals reflected the participant's priorities, not necessarily what the HN wished for the participant. After the participant decided on their specific and detailed short- and long-term goals, the HN and participant worked together to outline objectives the participants would need to accomplish in order to meet their goals. An "End of Session" worksheet documented and tracked these goals throughout the twelve sessions (see Implementation Toolkit).

For each participant, HNs were expected to monitor between two to three participant-identified goals. Additionally, HNs were encouraged to use the SMART format in writing goals and objectives. This helped maintain consistency across peers. The following describes the characteristics of goals and objectives using the SMART format[xxiii]:

S	Specific	Exact and concrete
M	Measurable	Observable or tangible
A	Achievable	The participant is willing to work towards the goal
R	Realistic	The participant is able to accomplish the goal
T	Time	Have a deadline for each goal

Navigator Note… on setting goals:

Finding issues that the client thought were important to address, even if they were not goals that were explicitly identified, was key. Work WITH the client to find ways to address issues and set short- and long-term goals. It was important for the client to understand that he was the

driver of process and that there [were] no time restraints on his progress. Once we identified the issue and made a plan to address the issue, I would support [the] client in reaching the goal. If he needed more assistance, I would be more active in searching for resources or more concrete solutions for [the] client when possible.

4) Integrate Mental Wellness

Regularly check in on mental wellness readiness and/or utilization. The WITH U program improved the process by which Project ARK addressed behavioral health needs of clients in HIV care at the three Washington University HIV clinics. WITH U administered detailed assessments (PHQ-8, GAD-7, PCL-C, and CRAFFT) at baseline, six months, and 12 months to identify psychosocial needs and struggles with mental health. Participants that screened positive on these assessments were automatically referred to mental wellness services. Additionally, the results of these assessments were used to tailor the peer navigation sessions. Participants were also offered immediate linkage to mental wellness services during enrollment. This immediate connection allowed staff to build rapport with participants and begin work together on day-one of enrollment into the program.

If not connected to mental wellness services during enrollment, HNs provided warm hand-offs, facilitated referrals, paired with education and motivational interviewing, to connect participants to available behavioral health resources during the program. Through introductions to staff, addressing perceptions of mental wellness services, providing reminders for appointments, and accompanying participants to their sessions, HNs addressed barriers that prevented participants from using available mental wellness resources.

A standing referral into mental wellness services was reviewed during each health navigation session and monitored via a shared social services documentation system. The WITH U evaluation team collected process measure data for the integration of mental wellness services.

Navigator Note… on referring to mental wellness services:
A common pitfall can be referring participants to mental wellness services due to a score on a standardized instrument without first assessing client's willingness to work on mental wellness - if they were interested at all. What worked was allowing participants to ask for mental wellness services versus automatically referring them due to scores for depression/anxiety. Also, sharing personal stories with my own engagement with mental wellness services may have helped clients who were contemplating engaging with mental wellness.

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5) Conduct Case Conferencing

Create a routine time and space to bring all members of the multi-disciplinary team together to focus on participant's needs. As part of WITH U, staff held monthly case conferencing meetings. This provided an opportunity for the HNs to lead discussions with the MCM, mental wellness specialist, and other care team members around the participants that participated in the

program. HNs spent approximately ten minutes discussing each participant. The remaining time was open for team members to discuss any participants that needed extra attention in more depth. The schedule below was also developed for different MCMs to meet with the team one week of each month. See *Weekly Case Conferencing Notes Template* in the Implementation Toolkit.

Monthly Case Conferencing Schedule	
1st Friday of the Month	Linkage to Care MCMs
2nd Friday of the Month	Adult/General MCMs
3rd Friday of the Month	Youth MCMs
4th Friday of the Month	Linkage to Care MCMs/Outside Agency MCMs

6) Enhanced Contact

Increase efforts to maintain an open channel for communication between the HN and participant. WITH U developed a schedule for regular and consistent reach outs, as well as texting inspirational quotations and general, friendly messages. Contact with participants also included follow-up on agreed-upon action items (e.g., medical appointments).

Adaptations Due to COVID-19

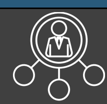
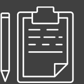
Recruitment - Due to COVID-19 pandemic, the Washington University team discontinued enrollments into WITH U as required by Washington University COVID-19 institutional policy in March of 2020. Recruitment resumed in June of 2020 when the COVID-19 protocols were changed by the University. Upon restart of recruitment, recruitment could take place remotely or in collaboration with the clinical team during a medical visit, if the potential participant was on campus for a clinical appointment. Bringing participants to campus solely for a research visit was restricted (see *COVID-19 Modification – Enrollment Protocol* in the Implementation Toolkit).

Program Delivery - Health navigation sessions were delivered 100 percent remotely, by text, phone, or HIPAA-compliant Zoom. All in-person meetings were discontinued and case conferencing between HNs, MCMs, and other multi-disciplinary team members was completed only over Zoom. Additionally, the WITH U team provided participants with the opportunity for extended health coach services past the 6-month program period to provide additional support services to participants due to stressors incurred by the COVID-19 pandemic. At the participant's last appointment (Session 12), the HN assessed if the participant needed additional health coaching services throughout the COVID-19 crisis (see *Verbal Consent for Service Extension* in the Implementation Toolkit).

Evaluation and Follow-Up - With changes that were made due to COVID-19 pandemic, follow-up survey sessions (discussed further below under Local Evaluation) had to be conducted

remotely via a secure Qualtrics platform. In addition, the WITH U team elected to have the staff member administering the survey stay on the phone/Zoom call with the participant while they completed the emailed Qualtrics survey. This presence allowed for prompt addressing of any issues that came up and ensured that the participant stayed on task and completed the survey. Also, the project was approved to provide Walmart and Target e-gift cards that could be emailed directly to the participant after completing each survey. This format was very popular among participants, as the card was directly accessible on their phone for online or in-person shopping.

Challenges in completing intervention sessions with participants also occurred due to the COVID-19 pandemic. Often, participants did not have full control over their schedules due to busy and irregular work schedules and family obligations (especially caring for a family member with coronavirus). Additionally, participants were more unstably housed and had more intermittent phone service than before the COVID-19 pandemic.

COVID-19 Impact		
 Recruitment	Program Delivery	 Evaluation & Data Collection
Suspension of, or limited access to, in-person medical appointments and services prevented in-person study recruitment: ➢ University shut down ALL research activities for two months ➢ Clinic was temporarily re-purposed as the COVID-19 response clinic ➢ Fewer participants were scheduled to allow for social distancing and cleaning ➢ MCMs were prohibited from seeing participants in person Participants were hesitant to enroll because of unpredictable schedules and life situations (job changes, caring for family, etc.).	Participants experienced more difficulty meeting basic needs: ➢ Housing was threatened, jobs were lost, job hours were severely reduced ➢ Stress associated with these losses presented additional barriers to participants receiving mental wellness services More positively: ➢ Stress and isolation due to COVID-19 increased the desire for connection with the HNs. ➢ COVID-19-related stress and trauma pushed participants to seek mental wellness services or other social supports.	Limited recruiting and enrollment created a need for change in the evaluation plan: ➢ A lower than anticipated number of participants resulted in insufficient power to draw conclusions from quantitative analyses ➢ The Evaluation team added a qualitative evaluation Unpredictable schedules and life changes made completing participant surveys in a timely fashion more challenging. Competing priorities for participants often made meeting basic needs a higher priority than participating in the WITH U intervention.

Local Evaluation

Local Evaluation Overview

The local evaluation sought to determine if the addition of an intensive health navigation intervention impacted health outcomes along the HIV care continuum compared to the regular standard of care for BMSM ages 18-29 who receive their HIV medical care from Washington University.

The smaller than expected number of participants that were enrolled in WITH U, due to the COVID-19 epidemic, did not provide enough power for statistically significant findings. Therefore, a qualitative evaluation was added to collect insights into participant experiences with the program, successes, and challenges. As such, the addition of a qualitative evaluation resulted in a mixed-methods local evaluation.

Multisite Evaluation

The MSE, which was directed by the Evaluation and Technical Assistance Provider for the SPNS Initiative, assessed implementation processes, intervention services and participant-level outcomes, and intervention costs. Self-reported participant survey data, encounter data, and clinical outcomes data collected for the MSE were available for analysis in local evaluations.

Logic Model

Program: WITH U Logic Model

Situation: HIV health disparities among young BMSM are often the result of a complex intersection of racism, discrimination, psychosocial cofactors, and low health literacy. Employing a peer-based health navigation program, that attends to behavioral health needs, health literacy, and linkage to services and psychosocial support through client goal setting activities, will improve health outcomes.

Inputs	Outputs		Outcomes -- Impact		
	Activities	*Participation*	Short	Medium	Long
WITH U Project Coordinator, Project Assistant, Two full-time Peer Health Navigators, Peer Supervisor Behavioral Health/Mental Wellness Expert Psychiatrist Substance Abuse Counseling Medical Case Management team Treatment Adherence Specialist Infectious Disease Medical Clinics Curricula: Peer Health Navigation, Motivational Interviewing, Supportive Counseling, Brief Interventions Education tools, self-awareness exercises Social Service Referrals	Health Navigators Trained: Motivational interviewing, harm reduction, HIV and healthful living, community resources, trauma-informed care, mental health and addiction screening Participants are screened and contacted by health navigation staff Assessment for mental health needs and acuity Referral Develop goals around education, support, and navigation Brief Motivational Interviewing Health Education Adherence and Engagement Counseling Self-Awareness Exercises Case Conferencing Follow-up and Monitoring	YBMSM with HIV (18-29) YBMSM newly diagnosed with HIV in last year YBMSM re-engaging in HIV care YBMSM with a not kept medical visit in last 6 months YBMSM with HIV viral load >200 copies YBMSM with HIV who score 5 or more on PHQ-9 YBMSM with HIV who score 10 or more on GAD-7 YBMSM with HIV who score 4 or more on PCL-C YBMSM with HIV who score 2 or more on CRAFFT YBMSM with HIV who smoke marijuana or other substances YBMSM at risk of falling out of care YBMSM with a recent history of sexually transmitted infection	Increased access to peer and social support Increased awareness of HIV self-management and health care navigation Increased knowledge of available HIV/AIDS resources Produce effective strategies for assisting YBMSM with treatment adherence Increased feeling of support for emotional well-being	Increased utilization of mental wellness and support services Reduced HIV medical visit no-shows Increased retention in HIV medical care Increased health literacy Increased number of persons who have an undetectable viral load Decreased acuity of HIV resource needs Reduced lapses in HIV medication refills Improved engagement and retention rates in HIV medical care	Improved Quality of Life and Decreased Risk of Transmission of HIV

Assumptions

- YBMSM with HIV are looking for mental health services and other social support services to navigate life (NASTAD-CEBACC December 2014)
- In-office interventions can be transformed for online delivery (Pachankis et al., 2013)

External Factors

- Social determinants influence the HIV care continuum before a diagnosis is even made (NASTAD, May 2014)
- Trauma and systematic racism experienced by youth of color in the St. Louis region, as highlighted by the 2015 DOJ report following the unrest in Ferguson.

Quantitative Evaluation

WITH U participants completed a computer-assisted self-report survey at their time of enrollment in the program, as well as at two, six, and 12-months post-enrollment. These data were merged with participants' medical record data, which included viral load and kept HIV medical appointments to perform outcome and process evaluation. Overall, data were collected from multiple sources illustrated in the table *Data Collection and Reporting* below, which included medical record extraction, social service documentation and notes, and self-administered quantitative surveys.

- Outcome Evaluation – focused on HIV care continuum measures, specifically viral suppression and retention in HIV medical care.
- Process Evaluation –
  - The MSE survey (i.e., BMSM-Patient Survey (BMSM-PS)) and local evaluation tools were administered via Qualtrics at baseline, six months, and 12 months. A local evaluation survey was conducted at two months, which was the end of the intensive weekly intervention with the HN.
  - Additional process measure data are listed in the table below.

Data Collection and Reporting: The table below illustrates the data collection points, systems, and reporting frequency.

Evaluation Category	Type of Data	System	Collection Frequency	Reporting Frequency
Outcome and process	Local eval – social determinants, behavioral health, subset of Peers for Progress consensus evaluation measures	Qualtrics	Baseline, 2 mos, 6 mos, 12 mos	As needed for progress reports
	Medical (ART Rx, viral load, HIV med visits)	EPIC	Every 6 mos	Twice annually
Process	MSE (BMSM-PS)	Qualtrics	Baseline, 6 mos, 12 mos	Twice annually
	Exposure (Dose)	SCOUT*	Daily entry, monthly export	As needed for progress reports or other dissemination activities
	Behavioral Health at WUSM	SCOUT		
	Topics covered in HN sessions	Healthie**		

** SCOUT is a secure, web-based, shared statewide client database for tracking and reporting Ryan White services*
*** Healthie is a HIPAA-compliant practice management and telehealth platform used by the HNs as the primary documentation system for WITH U session notes and activities.*

Quantitative Analysis:

Frequencies and means were used to describe the sample, including rates of mental health problems, experiences of violence, and other psychosocial risk factors. Means were also used to evaluate participant satisfaction with the intervention. Bivariate Spearman correlations were used to examine the associations between number of sessions attended and viral suppression, and between number of sessions attended and expressed need to address social determinants of health and mental health status.

Qualitative Evaluation

A team of three researchers conducted semi-structured, in-depth interviews over Zoom in Program Year 3. The interviews took place with a subset of participants (n=22) and included questions that explored participants':

- Views on the intervention,
- Analysis of the HN position,
- Work on personal goals,
- Engagement with the program, and
- Experience around the three core tenants of health navigation: education, support, and navigation.

Additionally, they collected information on the impact of the COVID-19 pandemic.

Interviews were also conducted with the HNs who delivered the program. These HN interviews were designed to gather perspective on the development and implementation of the WITH U program and how the HN position was integrated within the larger RHWAP system at WUSM. The HNs were also prompted to provide feedback on lessons learned, challenges, and recommendations for continuing or replicating the program in the future. The qualitative survey tools can be found in the Implementation Toolkit.

Qualitative Analysis:

Data analysis employed a directed content approach.[xxiv,xxv] A directed content analysis approach is appropriate for this study since prior research suggested topics that were likely to emerge during analysis. In total, three coders participated in our analysis. The lead researcher was an expert in HIV care and prevention with young MSM, and a second researcher was an expert in qualitative research methods. A third coder was a mixed-methods data analyst at Washington University and a former student of the second qualitative researcher during their Master's degree program.

Analyzing these data involved an iterative process of coding, inter-rater reliability checking, conferencing, codebook revisions, and thematic analysis. Initial rounds of coding included a combination of on-paper coding and coding using NVivo 12 Pro software. Inter-rater reliability checks and coding conferences were conducted after each round of coding was completed. Inter-rater reliability was high overall and coding schemes were adjusted as needed to resolve

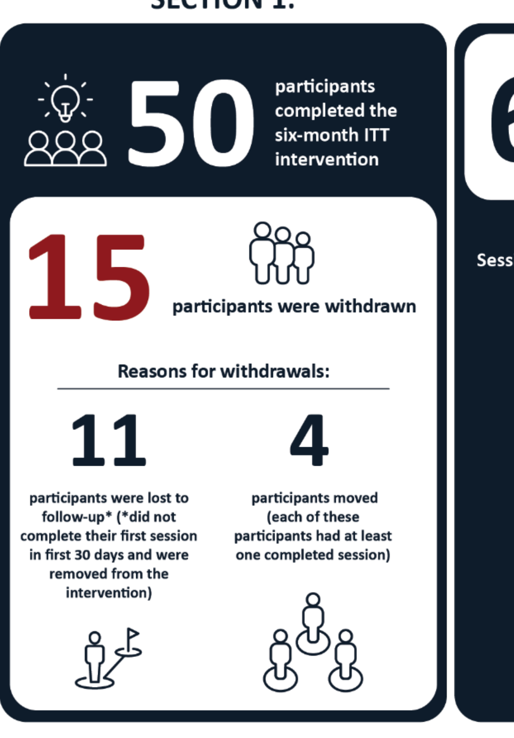
any discrepancies. Coding conferences were held on Zoom and involved the use of the Lucidchart website as an effective substitute for wall displays.[xxvi]

Once the data were condensed into a final set of codes, any codes containing 30 or more references were recoded as synthesized transcripts, allowing further nuances and patterns to emerge. Finally, summaries of each thematic code were drafted and representative quotations were selected.[xxvii]

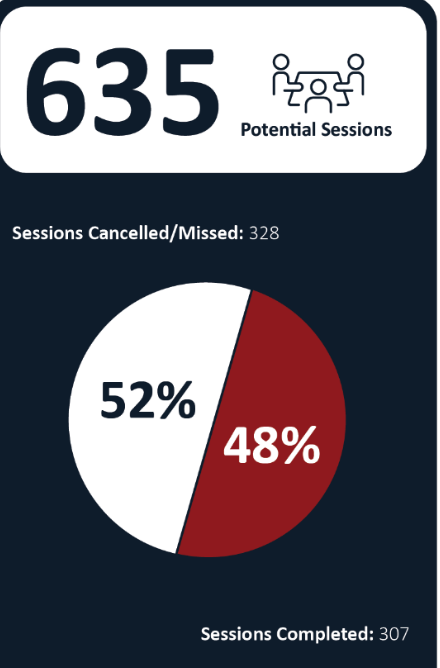
Intervention Outputs

Intervention Participation

SECTION 1:



SECTION 2:

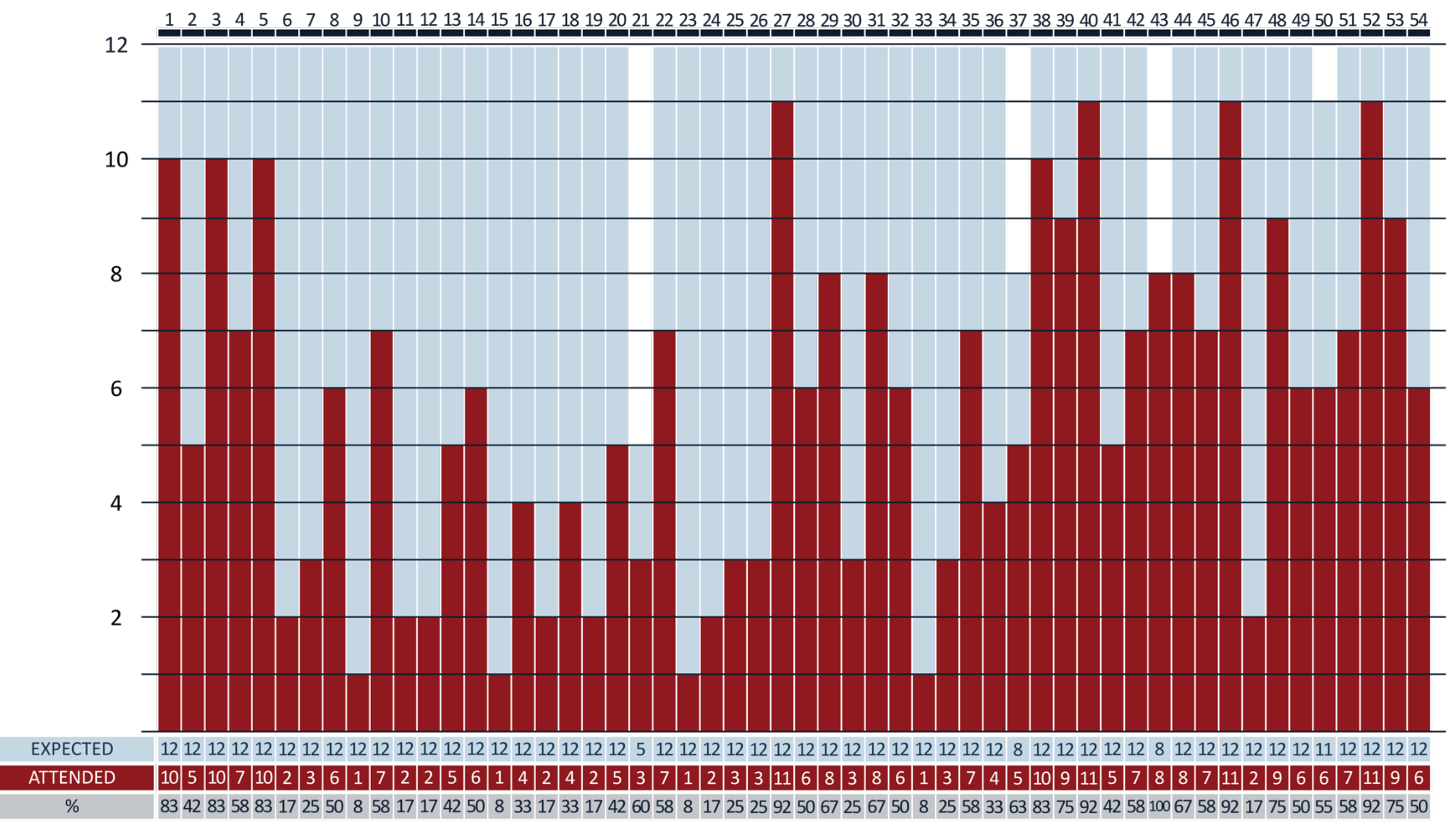


SECTION 3:

Of the 50 who completed the intervention: 29 consented to continuation of HN services past six-month period (discussed previously in Adaptations Due to COVID-19).

Intervention Dosage

Attendance Rate by Participant:



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
EXPECTED	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	5	12	12	12	12	12	12
ATTENDED	10	5	10	7	10	2	3	6	1	7	2	2	5	6	1	4	2	4	2	5	3	7	1	2	3	3	11
%	83	42	83	58	83	17	25	50	8	58	17	17	42	50	8	33	17	33	17	42	60	58	8	17	25	25	92

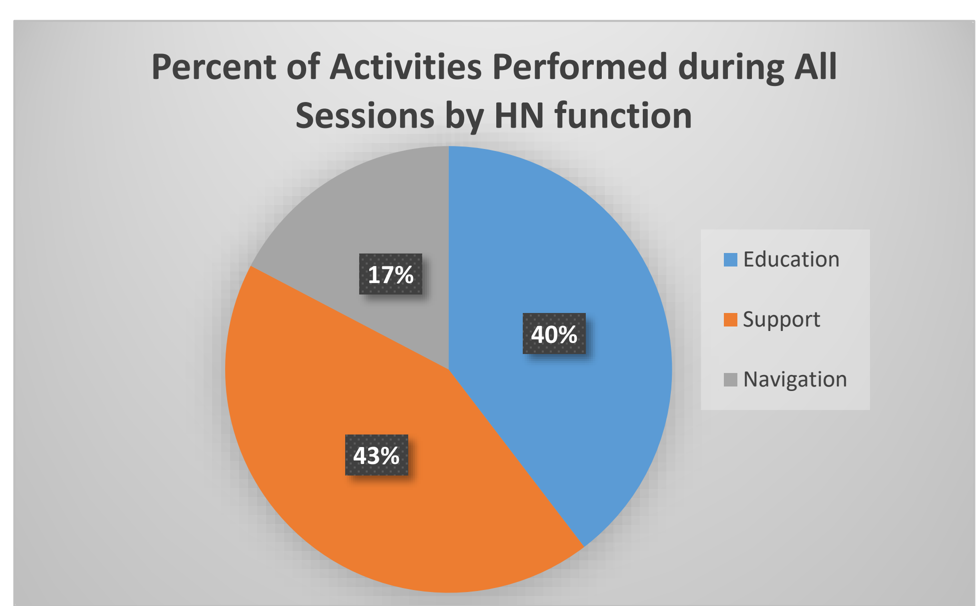
	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
EXPECTED	12	12	12	12	12	12	12	12	12	8	12	12	12	12	12	8	12	12	12	12	12	12	11	12	12	12	12
ATTENDED	6	8	3	8	6	1	3	7	4	5	10	9	11	5	7	8	8	7	11	2	9	6	6	7	11	9	6
%	50	67	25	67	50	8	25	58	33	63	83	75	92	42	58	100	67	58	92	17	75	50	55	58	92	75	50

Participant Attendance by Session:

	SESSION NUMBER	PARTICIPANTS ATTENDED (%)
DAILY SESSIONS	1	54/65 (83.1%)
	2	30/54 (55.6%)
	3	22/54 (40.7%)
	4	18/54 (33.3%)
	5	18/54 (33.3%)
	6	18/54 (33.3%)
	7	22/54 (40.7%)
	8	18/54 (33.3 %)
MONTHLY SESSIONS	9	29/51 (56.9%)
	10	25/51 (49.0%)
	11	26/51 (51.0%)
	12	27/50 (54.0%)

*Incentive given at 2 month point – often corresponding with session 9

Education/Support/Navigation:



Navigation

HNs, both independently and through collaboration with MCMs, assisted participants in navigating care and other support services. However, this guidance accounted for less than a fifth of the topics that were discussed during WITH U sessions.

Education:

HNs acted as important sources of information for participants during WITH U sessions. The most common educational topic covered by the HNs was medication/HIV treatment. Additionally, they commonly covered safer sex and prevention topics, mental wellness, and general health literacy (i.e., providing HIV 101, helping to understand lab values, and demystifying clinical care.

Support:

During WITH U sessions, the HNs provided important elements of support, including encouragement, stress management, emotional support, empowerment, and disclosure support. The figure below demonstrates how frequently and the various types of support provided. HNs provided support during 73 percent (225/307) of all completed sessions during the intervention period (10/15/19 – 7/21/21). Of the 54 participants that completed at least one session with their HN, 100 percent received at least one support element.

Non-traditional mental wellness provided by Health Navigators:

SUPPORT					
ENCOURAGEMENT	EMOTIONAL	BUILD RAPPORT	EMPOWERMENT	STRESS MANAGEMENT	DISCLOSURE
46% of all sessions	**44%** of all sessions	**43%** of all sessions	**26%** of all sessions	**25%** of all sessions	**8%** of all sessions
84% of all clients	**73%** of all clients	**75%** of all clients	**60%** of all clients	**62%** of all clients	**27%** of all clients

Participant Quote: “Sometimes we need that support to know that somebody’s still rooting for you.”

HN Quote: “So one thing that a lot of clients…most of the clients, if not all of them…really just needed support. And by support, it’s not even support about anything specific. They just needed somebody to talk to. And sometimes we would have sessions and not have conversations about HIV or medication. They just really wanted somebody to listen.”

Intervention Outcomes

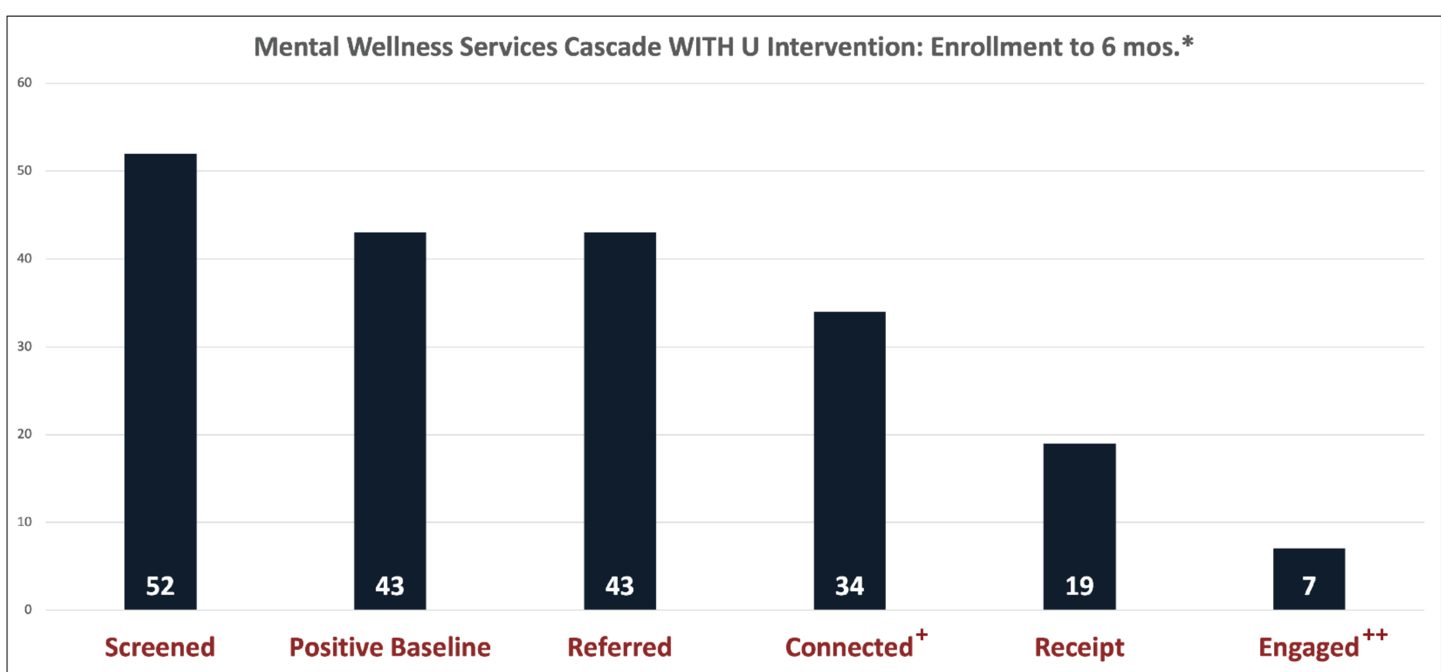
Quantitative Evaluation Results

Overall, participants reported high satisfaction with WITH U and attended an average of 5-6 of 12 possible sessions with HNs ($M=5.69$, $SD=3.05$). Attending a greater number of sessions was significantly associated with being virally suppressed at enrollment ($rs(50)=.36$, $p<.05$) and six month-follow-up ($rs(38)=.34$, $p<.05$), as well as greater concern about losing housing ($rs(54)=.29$, $p<.05$) and experiencing unemployment for at least three months in the last year ($rs(54)=.29$, $p<.05$). This aligns with qualitative findings that navigator support around instrumental needs was critical to participants. However, though participants identified mental health support from navigators as equally important, experiencing more depressive symptoms was significantly associated with attending fewer sessions ($rs(54)= -.32$, $p<.05$). Moreover, a switch to virtual sessions due to the COVID-19 pandemic was a barrier to engagement for some participants.

Behavioral health needs were assessed during the baseline, 6-month, and 12-month surveys using the PHQ-8, GAD-7, PCL-C-2, and CRAFFT screening instruments, referenced in the *Implementation* section. Psychosocial findings from the screening instrument at baseline are shown in the table below.

Psychosocial Risk Factors	N (%)
Depression (PHQ-8 ≥ 10; last 2 weeks)	17 (26.2)
Anxiety (GAD-7 ≥ 10; last 2 weeks)	17 (26.2)
Bothered by re-experiencing past stress (moderately or higher)	30 (46.2)
Bothered by feeling upset when remembering past stress (moderately or higher)	28 (43.1)
Possible Substance Use Problems (CRAFFT ≥ 2)	49 (75.4)
Used marijuana or other recreational drug in last 12 months	45 (69.2)
Engaged in binge drinking in last 12 months	45 (69.2)
Felt like alcohol or drugs are causing problems in life	12 (18.5)

Mental wellness services (MWS), which are behavioral health services provided by an in-house licensed clinician, were offered to all participants that screened positive on any of the screening instruments. The WITH U program effectively referred and connected participants with MWS while in the 6-month intervention. However, as shown in the mental wellness cascade below, only 44 percent of those referred to MWS received therapeutic services (Receipt: had at least one completed therapeutic encounter while in the intervention) and even fewer (16 percent) remained engaged in mental wellness services (Engaged: had at least four or more completed therapeutic encounters). The continuum below illustrates how participants with a positive screening moved through the mental wellness services.



*To be included in this Mental Wellness Services (MWS) cascade, the client had to complete the 6 mos., intent-to-treat intervention as of 9/17/2021.

+8 of the 34 participants were connected to MWS prior to baseline positive screen on PS.

++5 of the 7 engaged participants were recipients of therapeutic MWS prior to baseline positive screen and referral.

Qualitative Evaluation Results:

WITH U qualitative evaluation results were organized into four primary categories: 1) program impact and helpfulness; 2) COVID-19 impact; 3) engagement; and 4) recommendations. Major themes from each of these categories are described below. Additionally, a full report of the qualitative findings with additional participant and HN quotations can be found in the Implementation Toolkit.

Program Impact & Helpfulness: One of the primary benefits identified by participants of the WITH U program was emotional support. This included participants conveying the sense that they were *"not alone,"* reassurance from HNs regarding access to general support, instrumental resources, and mental health services, and an increased sense of self-efficacy and well-being. One participant explained:

> *"[My HN] helped me with self-esteem, like confidence, attitude – having a different outlook on life and approach. Just having a good sense of well-being because I knew that I have people that will help…someone that understands what you need to be human."*

Although participants appreciated referrals to mental health resources, HNs reported that WITH U participants sometimes did not follow through with those referrals because they preferred to discuss their problems with their HN. However, the HNs described not feeling prepared to offer mental health counseling. One HN stated,

> *"A lot of the issues that clients have rooted from family issues that they have not unpacked yet. And it's caused them to do drugs and it's caused them to seek love in*

> *other places. It's caused them to be rebellious. It's things that happened to a lot of my clients as children growing up, that's traumatized them. And a lot of my clients need to unpack that. And I can't unpack that sh**. One day eventually…cause being in this field, I said, 'You know, maybe I do want to be a counselor or a therapist, just a little bit.' But right now, I'm only your big brother...They really, really, need some mental health specialist."*

In addition to emotional support, participants described the helpful nature of the goal-setting framework used by HNs to structure the program. A majority of goals focused on addressing social determinants of health or improving one's overall health.

Other helpful components of the WITH U program identified by participants included gaining knowledge and life skills and accessing instrumental support. Some of this knowledge was about medical care, and other knowledge and skills were related to other parts of life, like expressing difficult emotions. Instrumental support received by participants centered around addressing social determinants of health and involved referrals and resources, reminders, and health literacy. For example, one participant explained:

> *"[My HN] even helped me with problem solving for my rent assistance when I needed it and my utilities. He was able to get in contact with [my case manager] the same day."*

Additionally, one of the HNs explained the importance of addressing social determinants of health to improve medical outcomes for WITH U participants:

> *"[O]ne of the biggest things that I realized is, mostly people don't give a sh** about taking medicine if the rest of their world is messed up[…] they don't have a job, they don't have a car, they don't have no money."*

Finally, participants found their relationship with their HN to be a helpful component of the program. Specifically, WITH U participants emphasized their HNs' availability, personalities, and similar life experiences as being vital to their positive experiences. The majority of participants explained that working with a HN ensured they had someone "*that's always there*." HNs achieved this feeling for their participants through open-door policies, acting as listening ears whenever needed, and regularly checking in with participants even when the participants did not respond. Some participants mentioned that while they do not check-in with their HNs regularly or may not have seen the value of having a HN before starting the program, knowing that there is a person there for them to rely on when they need support in any kind of way makes a big difference for their sense of wellbeing.

COVID-19 Impact: The COVID-19 pandemic emerged in the United States during the implementation of the WITH U intervention. Participants explained that the pandemic affected their employment as well as their personal/emotional health. Employment impacts included physical and emotional stress, as well as under-employment and financial strain.

Personal and emotional impacts were framed negatively and positively by participants. Some participants described needing to manage difficult life circumstances during the pandemic, such as loneliness resulting from social distancing. As one participant described:

> *"It takes away like, the humane feeling of like, being around another person. It feels very constricted, in a sense. Like, "Oh, my gosh. I have to live my life through a screen," type of feeling. And it doesn't feel all that good to not have so much human interaction sometimes, because you do get lonely. But more importantly, it's very easy to be one of those people that become really withdrawn…like withdrawn from the world."*

However, participants also described resilience through the pandemic. This included adapting to new communication technologies and finding purpose in new career paths.

> *"I think we're kind of managing it pretty okay…People still gotta get up, try to be nice, do the best thing they can, and still live."*

Program Engagement: When asked about engagement with the program, participants discussed their satisfaction with their level of engagement, preferences for how to communicate with their HNs, and barriers to engagement. When asked about the frequency of contact with their HNs, many participants expressed a desire for more frequent communication, especially following the transition from weekly to monthly contact after the first four weeks of the program. However, other participants reported being satisfied with the frequency of contact with their HNs.

Barriers to engagement in the WITH U intervention were reported by a small number of participants and included erratic work schedules, lack of readiness to change, and refusing help. As one participant explained:

> *"At first my schedule was up in the air with my other job, so I didn't really have set off days. So we have to schedule and kind of scramble around that."*

When asked about preferred method of communication, approximately seven participants reported a preference for in-person communication with their health navigator, four preferred Zoom or FaceTime calls, four preferred phone calls or texting, and six reported being adaptive to whatever communication medium was needed. Participants who reported being adaptive to different communication mediums explained that their relationship with their HNs was more important than how they communicated with each other. HNs reported that several participants did not find Zoom to be an acceptable virtual format and would prefer to use FaceTime. However, Zoom was required for video conferencing since it can be designed to be HIPPA compliant and FaceTime cannot.

Finally, participants and HNs described the impact of COVID-19 pandemic on program engagement. The onset and rapid spread of the COVID-19 pandemic in the United States necessitated a move from in-person to virtual delivery of the WITH U program. This meant that participants engaged with their HNs primarily through Zoom and FaceTime chats, phone calls,

and text messaging. Some reported that virtual engagement was more convenient, and others reported being able to adapt easily to the transition.

Although many participants were satisfied with virtual delivery of the WITH U intervention, some reported a strong desire for in-person sessions. Participants explained that in-person sessions led to improved relationship-building, reduced isolation, and avoided technological difficulties.

> *"I think Covid played a lot into all of this, because I do believe that if we were able to sit face-to-face, [my health navigator and I] could build a better connection with each other. But because of the Covid restrictions, we don't…"*

Recommendations: When asked about possible improvements to the program, approximately one-fifth of participants said the program was perfect the way it is. Of those who had suggestions for improvement, more than one-quarter of participants wanted more contact or connection with their HNs. These remarks were often made in reference to the program model where contact decreased from weekly to monthly.

Participants also suggested creating structures that would offer a sense of community with other program participants who have similar experiences. For example, some expressed a desire for informal in-person events while at the same time acknowledging that others might not be comfortable due to confidentiality/anonymity concerns.

HNs suggested that WITH U could be improved by increasing the theoretical, training, and collaborative team structure of the program. One HN explained that tailoring the program to each individual participant using the Stages of Change theory would likely improve engagement. They also suggested using other theories, such as the Theory of Planned Behavior, Cognitive Behavioral Theory, and Dialectical Behavioral Theory, to ground their work with program participants.

In addition to regular training, HNs reported a need for peer support among HNs. One HN explained,

> *"Other team members that don't necessarily operate with clients in the way that we do may not understand. And they may not understand the very high potential for burnout that we have of doing this job with multiple clients, day in and day out. You're giving yourself and talking about your past traumas. You're talking about your HIV diagnosis. You're talking about how you have some of the same problems that they have."*

Finally, HNs stated that improvements in care team collaboration could help them better serve the program participants. One recommendation was the standardization of regular case conferences so everyone on a participant's care team has the same knowledge about the participant. HNs also suggested including a mental health specialist as part of the care team for every participant to reduce feelings of stigma around mental health screening and referral.

Lessons Learned and Best Practices

Implementation

Several lessons were learned during the implementation of WITH U. Below we highlight best practices including facilitators to successful implementation and challenges encountered during the 3-year program.

IMPLEMENTATION	
Challenges/Lessons Learned	Facilitators/Best Practices
Intensive, long-term services are a challenge for this population and overly structured health navigation programs may inhibit participation when not allowing for participant-directed timeframes and activities.	Some participants prefer to receive health navigation support as an "on-call" service to attempt to quickly resolve of identified problems. Be flexible and consider a tiered approach to better meet participant's needs.
Standard therapy may not to be a good fit for many of the participants targeted by this intervention or BMSM in general.	Peer HNs provide critical emotional support in the absence of mental wellness engagement. HNs should regularly communicate their professional limitations and remind participants of the availability of mental wellness resources.
Some participants are not ready to set goals and actively work on their care and treatment.	Assess and address participant readiness to change for meaningful engagement.
Peer-based HNs are intimately impacted by the work that they do and have a high potential for re-traumatization and burnout.	Peer professionals need structured supervision and support (both professional and emotional), similar to any other professional working with this population (e.g., doctors, therapists, and MCMs).
Participants were heavily impacted by the COVID-19 pandemic. Participants reported that the pandemic negatively affected their wellbeing, employment and financial status, ability to manage difficult emotions, and life circumstances.	Participants suffering the effects of the COVID-19 pandemic (e.g., escalating mental health concerns, employment loss, food insecurity, loss of loved ones) attended to basic needs—food, housing, employment, etc. These social determinants of health were powerful.

Participant Quote: "It takes a lot of energy and time. You have to really want to do it… to be committed to it."

Participant Quote: "I have definitely been referred to [the housing program] a couple of times. When I was going through a couple financial crises and especially when COVID-19 started…I lost my job and things like that, just due to the pandemic. So the [HN] were very present throughout the whole… COVID-19 pandemic…. They have really been present, just want to ensure that I'm okay. Like, "Hey, are you eating? Do you have a place that's warm? Are you safe?" And things like that."

> HN Quote: "So one thing that we learned is that some clients…well, a lot of our clients…didn't engage in mental wellness services, because they felt that the HN were filling that void for them, which is kind of…I think it's good, but it's also kind of unfortunate, because there is… We're not trained in the way that the therapist is trained. And so like, I can give you my opinion about how I feel about something or I can kind of respond in a way to help you to hear what you want to hear, but I'm not necessarily changing the way that you think. I'm not…I can't offer them what a therapist can offer them."

Additional Facilitators and Best Practices

- Educating clinical providers to embrace, trust, and accept the use of HNs is important foundational work.
- Specialty caseloads (e.g., linkage to care, lost to care populations) and the case managers that work with them benefit from intense collaboration with a HN.
- Providing opportunities for remote communication allows more flexibility for all team members to effectively reach participants.
- A shared documentation system across multiple disciplines is important. Documenting social service activities in the electronic health record (EHR) helps medical providers be aware of personal circumstances and reinforce plans at medical visits.

Mental Health Key Takeaways

The WITH U program existed in the grey area between emotional support, as provided by peer-based HNs, and professional mental wellness services, provided by a licensed mental health practitioner. This work has led to considerations for how we structure our mental wellness program and provide mental wellness services to YBMSM. Seventy-three percent of the interactions with participants by HNs were for support, defined as encouragement, stress management, emotional support, empowerment, and disclosure support. Trained peer HNs offering wellness support has been shown to be well received and accepted. When describing the WITH U program in general terms, most interviewees emphasized their HNs' availability and personalities as being vital to their positive experiences. The majority of participants explained that working with a HN ensured they had someone "that's always there."

> HN Quote: "Support was really the bulk of the WITH U program. That is pretty much the backbone of this program, to be honest."

Additionally, standard therapy may not to be a good fit for many of the participants targeted by this intervention or BMSM in general. Despite having a dedicated process for successfully screening and referring participants to behavioral health care, on a whole, participants did not choose to engage in standard therapy sessions to meet their needs.

Certainly, peer health navigation served as an important link between mental wellness providers and MCMs. Case conferences among these team members can be leveraged to build

bridges and provide better informed care and treatment. Also, with the opening of the availability and acceptability of telehealth in a post-COVID-19 world, mental wellness work can happen anywhere – HNs and behavioral health providers can be where they are (i.e., in the office or at home) and deliver to the participants where they are.

Yet, is participating in traditional talk therapy really meeting our participants where they are? Perhaps a new model of mental wellness consists of well-trained and supported HNs. It seems unreasonable to expect a person with pressing social determinants of health needs—food, housing, inter-personal safety—to engage in therapy. Perhaps truly being present with a participant and listening to a person is the most affirming approach.[xxviii] Continued research on novel methods for meeting the emotional and behavioral health needs for YBMSM is needed.

Dissemination Activities

To Learn More:

Dissemination Goals: In coordination with the Evaluation and Technical Assistance Provider for this SPNS Initiative, NORC at the University of Chicago, Washington University has participated in the development of this Implementation Manual, Implementation Toolkit, trainings, and other dissemination products to promote replication of intervention components shown to improve health outcomes for BMSM with HIV. WUSM has committed to:

1) Develop materials for dissemination and share findings from the WITH U intervention
2) Promote the dissemination materials and support replication activities at sites interested in adopting aspects of WITH U or WITH U in its entirety
3) Conduct a mixed-methods evaluation and publish findings.

Intended Target Audience: Dissemination of lessons learned and best practices from Washington University's WITH U Project will help to build capacity and readiness of RWHAP and non-RWHAP recipient organizations to successfully engage, link, and retain BMSM with HIV in care and treatment that addresses their behavioral health and support service needs. Washington University will focus on disseminating to the following audience(s):

- Project administrators responsible for identifying and adapting programs for use at their institutions.
- RWHAP-funded organizations utilizing or hoping to utilize peer health professionals as part of their multi-disciplinary team.
- HNs in need of readily usable materials for enhancing their job performance.

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