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iVY: protocol for a randomised clinical trial to test the effect of a technology-based intervention to improve virological suppression among young adults with HIV in the USA

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ABSTRACT

Introduction Young adults with HIV (YWH) experience worse clinical outcomes than adults and have high rates of substance use (SU) and mental illness that impact their engagement in care and adherence to antiretroviral therapy (ART). The intervention for Virologic Suppression in Youth (iVY) aims to address treatment engagement/adherence, mental health (MH) and SU in a tailored manner using a differentiated care approach that is youth friendly. Findings will provide information about the impact of iVY on HIV virological suppression, MH and SU among YWH who are disproportionately impacted by HIV and at elevated risk for poor health outcomes.

Methods and analysis The iVY study will test the effect of a technology-based intervention with differing levels of resource requirements (ie, financial and personnel time) in a randomised clinical trial with an adaptive treatment strategy among 200 YWH (18–29 years old). The primary outcome is HIV virological suppression measured via dried blood spot. This piloted and protocolised intervention combines: (1) brief weekly sessions with a counsellor via a video-chat platform (video-counselling) to discuss MH, SU, HIV care engagement/adherence and other barriers to care; and (2) a mobile health app to address barriers such as ART forgetfulness, and social isolation. iVY has the potential to address important, distinct and changing barriers to HIV care engagement (eg, MH, SU) to increase virological suppression among YWH at elevated risk for poor health outcomes.

Ethics and dissemination This study and its protocols have been approved by the University of California, San Francisco Institutional Review Board. Study staff will work with a Youth Advisory Panel to disseminate results to YWH, participants and the academic community.

Trial registration number NCT05877729.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Intervention for Virologic Suppression in Youth (iVY) has the potential to impact HIV health outcomes and mental health (MH) and substance use (SU) among youth with HIV (YWH) who are disproportionately impacted by HIV and who experience more MH challenges than the general population.
⇒ iVY will enhance efficiency of care delivery because it provides a brief, out-of-facility, youth-friendly video-counselling and mobile health app to 18–29 years old that is customisable to the needs of YWH.
⇒ The study uses an adaptive treatment strategy to individualise the intervention to YWH based on their viral response to the intervention providing a differentiated care model which tailors care to individuals with the greatest need.
⇒ Given HIV-related stigma, the influence of the COVID-19 pandemic on MH and SU challenges, and other barriers to care, the use of video-counselling and provision of remote research and services will likely remain high.
⇒ The intervention will not be available to those who do not have a smartphone or who are Spanish speakers.

INTRODUCTION

Young adults with HIV (YWH) in the USA have the lowest level of virological suppression[1–3] compared with older age groups. They experience significant health disparities in HIV clinical outcomes,[4–8] including lower rates of antiretroviral therapy (ART) initiation,[8] suboptimal ART adherence[8–10] and retention in care,[11] and higher virological failure rates.[12] Lack of virological suppression is a major contributor to mortality, morbidity and secondary transmission events.[13 14] Additionally, mental health (MH) and substance use (SU) impact every step of the HIV care continuum from diagnosis to virological suppression[15–19] and exacerbate socioeconomic challenges of linkage and sustained

access to healthcare.[20–24] There is also an increased risk of SU disorders, psychiatric disorders and mortality with SU at a younger age.[25–27] Overcoming these barriers is key to improving life expectancy, HIV-related disabilities and quality of life.[28 29] Given the strong evidence for the influence of MH and SU on worsening HIV health outcomes, there is a clear need for increased access to and provision of MH and SU services. Despite the need to address these critical barriers to care among YWH, there is a severe shortage of MH professionals[30–32] and evidence-based interventions for YWH.[33 34]

Addressing this gap calls for interventions with differentiated or individualised approaches to tailor care to individuals with the greatest need. Adaptive treatment strategies (ATSs) involve adapting a treatment to an individual's changing needs using predefined decision rules,[32–36] making them patient centric by design and potentially reducing cost by only giving the appropriate therapy rather than a one size fits all approach.

Study objective

We describe the protocol for a study to assess the efficacy of a technology-based intervention on HIV viral suppression (primary outcome). Intervention for Virologic Suppression in Youth (iVY) aims to address MH and SU in a tailored manner using a differentiated care approach that is youth-friendly.[35] iVY combines two components to address SU and MH among YWH: (1) brief weekly sessions with a counsellor via a video-chat platform (video-counselling) to discuss MH, SU, HIV care engagement and other barriers to care[37 38]; and (2) a mobile health app called WYZ designed and developed using a Human Centered Design approach with YWH to address barriers.[39 40] The primary goal is to address important, distinct and changing barriers to HIV care engagement (eg, MH, SU, forgetting, social isolation)[41–44] among YWH.

METHODS AND ANALYSIS

Study overview and design

iVY is testing the effect of a technology-based mobile health app and video-counselling intervention in a randomised clinical trial (RCT) with an ATS[45–49] among YWH (18–29 years old). Individuals who are not durably virologically suppressed are randomised (figure 1) to video-counselling+app or standard of care (SOC). At 16 weeks, HIV virological suppression between the intervention and control arms will be compared using data from home-collected HemaSpot test kits. Through this study, we are (1) testing the efficacy of video-counselling+app versus SOC on virological suppression and (2) assessing the impact of video-counselling+app versus SOC on MH and SU. We are evaluating HIV virological suppression, MH and SU differences between the intervention versus control arms at 16 weeks. We are also (3) exploring an ATS to individualise the intervention by assigning the virological 'non-responders' in the intervention arm to intensified video-counselling+app for 16 more weeks,

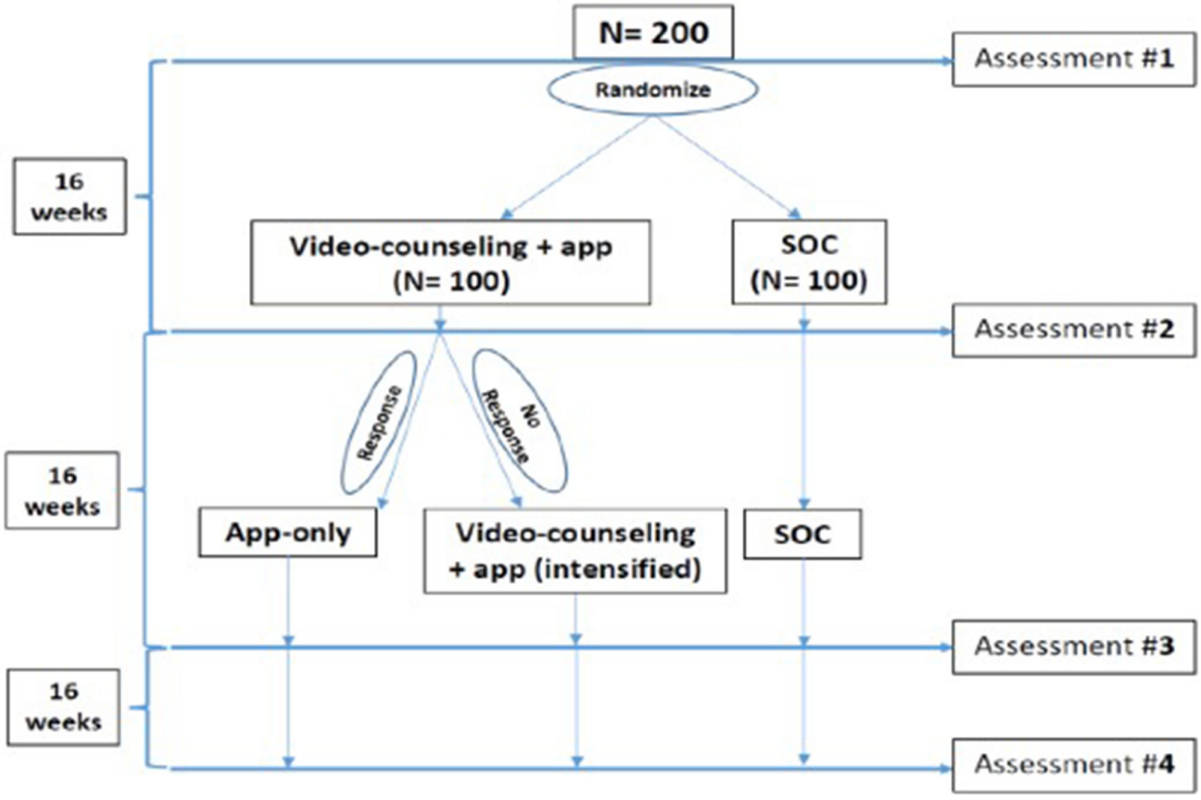

Figure 1 Overview of study design. SOC, standard of care.

and the virological 'responders' (responder=virologically suppressed; non-responder=virologically unsuppressed) in the intervention arm to continue only app use for 16 more weeks. Participants complete an assessment survey and home-collected viral load (VL) testing at baseline, 16, 32 and 48 weeks.

Study setting

We are working with AIDS Healthcare Foundation (AHF) to implement the study and recruit YWH receiving HIV primary care. In 2019, AHF served 1292 YWH in California, 927 (72%) of whom are in five AHF Healthcare Centers: Downtown Los Angeles, San Diego, Westside, Hollywood and Oakland. Among these 927 patients, 44% had a VL <200 copies/mL. Additionally, we are opening recruitment for YWH at other non-AHF CA clinics. All study activities are conducted remotely with previous methods successfully used by our team.[50 51]

Participant population

The study includes 200 YWH who are between the ages of 18–29, live and receive care in CA, have a lack of durable viral suppression (any HIV VL (≥20 copies/mL in the past 12 months), have access to a smartphone and speak English. We have chosen to include young adults aged 18–29 as they are in a distinct developmental phase with unique needs and challenges compared with individuals younger than 18 or older than 29 years or younger than 18. Those with a history of haemophilia or who are unable to conduct finger pricks at home for the VL test are excluded because participants are required to do at-home VL testing. Individuals with MH or SU challenges are included, unless their symptoms are too severe for them to safely participate in the study.

General study procedures

Recruitment

AHF is contacting patients from their database of YWH ages 18–29 who have a lack of durable viral suppression (any HIV VL (≥20 copies/mL in the past 12 months) to offer study information. Interested patients are handed off to the study team for further information, screening and enrolment; or they may be asked for permission to share their contact information with the study team to be contacted later. Non-AHF participants are recruited via social media and flyers posted at healthcare clinics serving YWH.

Screening, consent and enrolment

The study team screen interested individuals over the telephone to determine eligibility and enrol them in the study. Interested individuals are given adequate time to read the consent form; the study team member is available to answer any questions via phone. The consent form, to be signed electronically, includes information about potential risks and benefits, that participation is completely voluntary and will not affect SOC that participants receive, and that participants may withdraw from the study at any time. Any individual displaying MH or SU challenges that may impede the understanding and completion of consent is excluded and referred to appropriate services.

Randomisation

We are using a random number generator in REDCap (Research Electronic Data Capture) to randomise 1:1 allocation to intervention or SOC arms.[52] Participants are assigned to groups via block randomisation with block size permuted to promote group balance on covariates. Given the lack of an appropriate time-matched and attention-matched control group and need to establish generalisable efficacy, we are comparing the video-counselling+app arm to a SOC arm. The SOC arm includes the current care delivery model: regularly scheduled visits with a healthcare provider and lab testing every 3–6 months or more/less frequently, depending on the individual's HIV health outcomes (eg, viral suppression). The study team asks participants to complete the first study assessment. After completion of the survey, the participants will get randomised, and the study team will mail the participants' baseline VL home-collected test. The VL sample is collected via a HemaSpot HF device, which uses advanced dried blood spot (DBS) technology. HemaSpot-HF is an improved collection over the traditional DBS cards because it protects the sample from contamination, allows for safe transport and easy storage and shipment, and provides a rapid sampling mechanism that does not require drying.

Patient retention and incentives

Retention is supported through the collection of detailed contact information, short message service (SMS) messaging and incentives. We have monthly check-ins with participants during which we ask about app use, provide support for logistical challenges with the app and update any contact information. We also work with a Youth Advisory Panel (YAP) on maintaining and enhancing participant retention throughout the study. Incentives include $20 for completing the baseline survey, $50 for the 16-week survey, $40 for the 32-week survey and $30 for the 48-week survey; $40 for the baseline, 16, 32 and 48-week home-collected VLs, plus a $10 for VL kits that are returned on time. Incentives are distributed through Venmo or CashApp via a study account that uses a study-specific mobile phone number and email and is accessible only by the study staff. Participants are asked to provide their CashApp or Venmo username, which is verified. The default is set to 'private' so that payment information cannot be viewed by others.

Risks to participants

Risks to participants are monitored regularly by trained study staff and documented at each intervention session and study assessment. At each assessment, we review participant responses to examine acute need for referral to medical, MH or SU services.

Adverse events and auditing

In this study, we do not anticipate moderate, severe, life-threatening, disabling or fatal adverse events. Potential adverse events include loss of confidentiality or emotional distress.

Patient and public involvement

To inform study implementation and dissemination, we have identified 10 YWH from AHF Healthcare Centers in CA to form the YAP. YAP meetings are held two times a year virtually and last for 2 hours. YAP members review study materials and provide input/feedback about the intervention, research questions, recruitment and retention strategies, next steps and dissemination of findings. In addition to keeping the YAP updated about study progress, we discuss any implementation challenges, engagement, attrition and other issues to obtain the YAP's feedback to improve study implementation.

Intervention procedures

The intervention arm (video-counselling+app) receives 12 brief weekly counselling sessions (given over 16 weeks) with a masters level MH professional (eg, social worker), along with access to the WYZ app to use based on their needs. After 16 weeks, responders in the video-counselling+app arm continue to use the app only. Non-responders in the intervention arm continue with intensified video-counselling+app for 16 more weeks. The additional 16 weeks aims to reinforce counselling points by targeting participant-specific barriers to virological suppression based on the needs of non-responders.

Video-counseling

The goal of video counselling is to provide information, motivation and behavioural skills for dealing with MH, SU and HIV care engagement challenges to address mild–moderate MH symptoms or low–moderate levels of SU; and assist with linking/relinking to more extensive MH, SU and/or HIV treatment, as needed. The intervention tailors the counselling based on baseline factors as follows: (1) HIV care acuity: due to unsuppressed VL of all participants, each individual receives two core HIV sessions and sessions will be tailored based on barriers to achieving virological suppression; (2) MH acuity: based on elevated PHQ-9[53 54] (10+), GAD-7 (10+)[55] or PCL-5; (33+)[56] score or (3) SU acuity: based on elevated AUDIT (8+),[57] DAST (3+),[58] or monthly or more use of drugs (besides marijuana) or daily use of tobacco or marijuana as measured by ASSIST.[59 60] Individuals with 'high acuity' receive two core sessions related to HIV care (2A/B), MH (2A/B) and/or SU (3A/B), each. 'A' sessions assess barriers and build motivation, while 'B' sessions provide information and deliver health education. A and B core sessions map onto the Information, Motivation, Behavior (IMB) model,[61] which was used to develop the intervention.

For the remaining sessions, we use an integrated behavioural health and HIV care-focused approach to further the conversations in the core sessions. Participants choose from a list of menu sessions identified in the first session which allows the counsellor to spend more time on HIV care, MH or SU based on the participants' needs. In this manner, the intervention is tailored to the unique and changing needs of participants and can address other specific topics related to their experiences of racism, transphobia, stigma, discrimination, gender identity, racial/ethnic identity, classism, and current events.

SMS messages are used to enhance the intervention and for participant retention by: (1) assessment of completion of health goals (ie, behavioural skills) set during weekly sessions (eg, schedule appointment with provider); (2) provision of MH/SU or community resources based on participant's needs (eg, housing); (3) follow-up to ensure participant's linkage to MH, SU or HIV care; (4) reminder of video-counselling session and (5) monthly check-in to update contact information.

Fidelity to intervention

A session fidelity checklist is completed for each session to ascertain whether the focus area and barriers were identified, education/information was provided, motivation was enhanced and problem-solving was initiated. The study team assesses intervention fidelity during weekly meetings with the counsellors to review each session's length, technical issues, topics covered, goals established, and narrative progress notes.

Counsellor training

Prior to conducting sessions, counsellors participate in >25 hours of interactive training to learn the protocol and intervention manual intimately and role-play pre-prepared vignettes. Counsellors must attend the entire training and demonstrate proficiency of knowledge of the intervention manual.

WYZ app

WYZ was designed and developed using a human-centred design approach with a YAP, formative research with YWH, and is grounded in the IMB model.[39 40] WYZ contains three main features: My Health, My Community and My Team. Each of these features are described in more detail in table 1 and figure 2. Tailoring is achieved based on the individual's needs at a given time (eg, My Community may be used more if social isolation is a barrier). For the My Community feature, all original posts must be approved by research staff before posting. On a weekly basis, research staff review new responses to all posts to ensure that there are not any critical issues to be addressed. Any issues are brought to the study team's attention and referred to a clinical psychologist on the team if needed. Monthly check-ins help improve engagement through checking contact information and answering any questions.

Data collection procedures

Quantitative study assessments with home-collected HIV VL testing are done at baseline, 16, 32 and 48 weeks after enrolment and randomisation. Quantitative assessments collect information about sociodemographic

Table 1 WYZ features

Feature	Function	Barriers addressed
My Health	Set customised ART adherence reminders (B), refill/injection reminders (B), graph adherence over time (M), keep track of VL and CD4+ test results (I/M)	Too busy, forgot, changed my routine, ran out of pills, unstructured lifestyle
My Team	Increase access to community organisations and resources using the participant's geo-location (I)	Lack of access to MH and SU services or other community services, limited mobility
My Community	Allow users to interact with other YWH through moderated forums (M), stay up-to-date on health news (I), provide a calendar of community events (I)	Low health literacy, social isolation, stigma, lack of community support

ART, antiretroviral therapy; MH, mental health; SU, substance use; VL, viral load; YWH, young adults with HIV.

characteristics, SU, technology use, MH, HIV-related outcomes and experiences with the intervention for those in the intervention arm. All measures are described in table 2. REDCap is used for all data collection such as surveys, intervention implementation and clinical data.[52] REDCap is a secure web application for building and managing online surveys and databases, and data are stored and managed on a University of California San Francisco (UCSF) server.

Qualitative exit interviews

At 16 and 32 weeks, we will conduct semi-structured individual exit qualitative interviews with a sample YWH from the intervention arm, stratified by response or non-response (ie, suppressed or unsuppressed HIV VL) and levels of engagement (attended ≥80% of counselling session vs <80% attendance). The interviews explore (1) barriers/facilitators to intervention participation, (2) barriers/facilitators to intervention response/non-response, (3) need for future modifications, and (4) preferences for longer term support.

Security and confidentiality

All data are stored on a secure, HIPAA compliant, password-protected server. Participants' contact information and other identifying data are stored separately from other study data, the key linking names to study ID is stored separately and destroyed at the end of data collection, and all other study documents only have participant codes. Only the research team have access to participant identities. All data are de-identified prior to analysis and individuals will not be identified in any reports or publications of the research.

We use Zoom for video-counselling, which is the UCSF-preferred HIPAA-compliant video chat platform. We have developed study protocols related to video-counselling privacy and security. For SMS messages, study staff demonstrate how to set up privacy settings on smartphones, such as keeping SMS message previews from showing up on locked screens and adding a security code to lock the smartphone. For the WYZ app, we have partnered with the UCSF School of Medicine Technology (SOM Tech) team to maximise security. SOM Tech has built this app within best practices for developing HIPAA-compliant apps and has worked closely with the UCSF Enterprise Security team to review the app architecture in an iterative manner to ensure the highest level of security. All qualitative interviews are conducted remotely and audio-recorded via HIPAA-compliant web conference platform (eg, Zoom) with audio-recordings stored on a HIPAA-compliant server with access available only to select study staff. All audio-recorded files are deleted on completion of the study.

Data monitoring

A data safety monitoring board consisting of three external reviewers meet annually to review the research

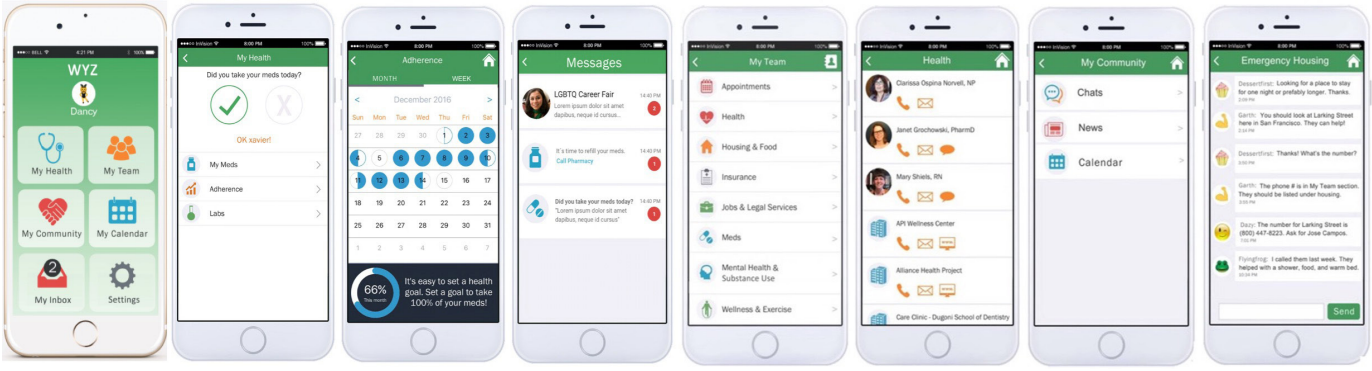

Figure 2 Mobile app screenshots.

Table 2 Outcome and descriptive variables

Variables		Items	Interpretation
Outcome			
1°	HIV viral load (VL)	Virological suppression using HemaSpot device	Suppressed VL: <400 copies/mL Unsuppressed VL: ≥400 copies/mL
2°	Mental health (MH)	Depressive symptoms: PHQ-9[64] (10 items; score=0–27)	Higher score indicates more depressive symptoms
		Anxiety: GAD[55] (7 items; score=0–21)	Higher score indicates more anxiety
		Trauma: PCL-5[65] (score=0–80)	Higher score indicates more trauma
	Substance use (SU)	DAST[58] (10 items; score=0–10)	Higher score indicates more drug misuse
		AUDIT[57] (10 items; scores=0–40)	Higher score indicates more alcohol misuse
		ASSIST[59]	Frequency of alcohol, smoking and SU
Other descriptive variables			
Demographics		Age, sex/gender, race/ethnicity, sexual identity, education, income, work, school, living situation, city of residence, ever homeless or incarcerated	
MH and SU		Type and frequency of MH and SU services ever received or being received; timeline follow-back method for more recent SU[90 91]; the Quick Inventory of Depressive Symptomatology (Self-Report) (QIDS-SR16)[92]	
Healthcare accessibility		Distance to get to HIV clinic, ease of getting appointments at clinic, ease of getting in touch with provider[93]	
Social isolation		PROMIS Item Bank[94] (14 items, score=14–70)	Higher score indicates greater isolation
Technology use		Use of technology to email providers, refill medications or making medical appointments, frequency of break in service or lost/stolen phone, reliability of service, access to Wi-Fi,[95] mobile technology vulnerability scale (MTVS),[96] System Usability Scale (SUS)[97] for WYZ	MTVS range=0–17 with higher scores indicating more vulnerability,[96] SUS range=0–100 and scores >68 considered above average[98]
Perceived engagement in HIV care		Index of Engagement in Care[99] (10 items, score=0–10)	Higher score indicates higher antiretroviral therapy adherence, clinic attendance, VL suppression
HIV knowledge		HIV treatment knowledge scale[100] (15 items, score=0–15)	Higher score indicates more knowledge
Engagement with provider		Healthcare provider engagement[101] (13 items, score=0–52)	Higher score indicates poorer engagement
Subsistence needs		Unmet subsistence needs[42 102] (5 items, score=0–5)	Higher score indicates more subsistence needs
Resilience		Brief resilience scale[103 104] (6 items; score=1–5)	High score indicates more resilience
App paradata		Number of minutes in app; change in app use over time; number of push notifications opened from those sent through the application; use of My Health (adherence tracking), My Team (identification of community services), My Community (chat with peers, use calendar)	

protocol and materials, evaluate the progress, and report on safety and concerns.

Study outcomes

The primary outcome is HIV VL using the HemaSpot-HF device.[62] We mail participants home test kits (including the HemaSpot-HF device, gauze, bandages, lancets, alcohol wipes and pre-addressed stamped envelopes) at baseline, 16, 32 and 48 weeks. After a finger prick, they place two drops of blood on the HemaSpot-HF device. The device dries in 1 min; participants then close the lid and mail the device to the laboratory. The laboratory uses the Abbott RealTime HIV-1 DBS assay with a lower limit of 400 copies/mL.[63] To minimise missing data, we request missing VL data (±1 month around the four VL time points) from participants' clinical electronic medical records. The secondary outcomes are MH (PHQ-9,[64] GAD-7[55] and PCL-5[65]); and SU (AUDIT,[57] DAST[58] and ASSIST[59]).

Quantitative data analysis

Frequency tables for all variables and measures of central tendency and variability for continuous variables will be used to characterise the sample. In addition to describing important sample characteristics, these descriptive analyses will summarise the app paradata listed in table 2, which will provide important information on overall app engagement and specific features used most. If the study arms differ significantly at baseline on covariates, we will use methods based on the Rubin causal model (eg, propensity scores, double-robust estimation) to obtain the effect estimates under the counterfactual assumption of balanced groups.[66–70] We will address missing data with multiple imputation.[71]

To assess efficacy of video-counselling+app versus SOC on virological suppression in YWH, we will compare HIV virological suppression of those randomised to the intervention versus control arms at 16 weeks. We hypothesise that at 16 weeks the odds of our primary outcome, virological suppression, will be higher for video-counselling+app intervention participants than for SOC participants. To test this comparison, we will fit a logistic regression model. To assess the impact of video-counselling+app versus SOC on the secondary outcomes, we will evaluate the MH and SU differences between the intervention versus control arms at 16 weeks. We will employ general linear modelling methods to test whether mean levels of MH and SU at 16 weeks are lower in the video-counselling+app group versus the SOC group. Demographic and prespecified covariates based on theory and literature will be included and moderated mediation will be explored using causal inference-based methods.

We will also explore differences between those who were (1) virological 'non-responders' in the intervention arm who received intensified video-counselling+app for 16 more weeks and (2) virological 'responders' in the intervention arm who continued only app use for 16 more weeks. Frequency tables for all variables and measures of central tendency and variability for continuous variables stratified by virological response status will characterise responders and non-responders on measures at 16 weeks including MH and SU. An exploratory multivariable logistic regression analysis will be performed on the subgroup of participants exposed to the intervention to predict which participants will be responders versus non-responders. Additionally, we will use logistic regression to explore whether responders versus non-responders at 16 weeks exhibit higher odds of virological suppression at 32 weeks.

Qualitative analysis

Data will be analysed using thematic and content analysis frameworks.[72] Data analysis will draw on an inductive approach[73] and by deductively applying codes developed from the interview guide. This dual approach will allow for themes to emerge from the data using inductive coding while also using an a priori template of code from which to frame the analysis.[74]

Power analysis

Power analyses were generated using NCSS PASS 2021[75] to compute the minimum detectable effect sizes for the proposed primary analyses. The study is beginning with 200 participants assigned to the video-counselling+app (N=100) intervention group and the SOC control group (N=100). Assuming 20% attrition based on our pilot studies[40 76] and prior research among YWH,[77] data from 160 participants will be available to test hypotheses. Assuming total N=160, α=0.05, power=0.80 and 44% in the control group virologically suppressed based on data supplied by AHF, we computed the minimum detectable OR, proportion difference (pdiff) and standardised proportion difference (h) for the proposed primary comparison, which yielded OR=2.46, pdiff=0.22 and h=0.44. For continuous MH and SU outcomes, we used the same inputs as above and computed the minimum detectable standardised mean difference d across the video-counselling+app and SOC groups, yielding d=0.45. Our proposed primary analyses can detect effects that are between small and medium.[78] In addition, a 22% increase in virological suppression or an OR of 2.46 is an effect size equal to or smaller than other studies among YWH or older adults living with HIV[79] and is clinically meaningful.

ETHICS AND DISSEMINATION

We received approval from the University of California, San Francisco Institutional Review Board to conduct this study and written consent from all participants. Reliance agreements were signed by RTI international and AHF. The study team will work with the YAP to disseminate results to YWH, participants and the academic community. A manuscript with the results of the primary study will be published in a peer-reviewed journal along with separate manuscripts for the secondary aims.

DISCUSSION

Our intervention protocol uses a tailored approached to impact engagement in HIV care by focusing on MH, and SU among YWH using a tailored approach, focusing on various barriers to care to different degrees, based on their changing needs.[41–44] Despite YWH experiencing more MH challenges than the general population substantially fewer interventions have been developed and evaluated in YWH compared with older adults.[33] Most intervention studies for YWH have been conducted with small sample sizes, limited follow-up times, and not examined impact of the intervention to sustain or improve MH.[33 80] While there are interventions for HIV prevention and SU among youth,[81–84] they are limited by requiring lengthy in-person sessions with a trained counsellor, involving the youth's families, focusing specifically on SU (vs a holistic approach), and were developed for younger adolescents. iVY is innovative because it provides a 'self-service' model that is customisable to the needs of YWH. Additionally, a recent review suggests the need for multi-component

interventions that go beyond health facilities to address social barriers to engagement in HIV care.[34] Thus, our study is significant and will enhance efficiency of care delivery because it provides a brief, out-of-facility, youth-friendly video-counselling and mobile health app to 18–29 years old with HIV, which focuses on HIV care, MH and SU, and connects participants to community resources to continue receiving MH and SU services, as needed.

We acknowledge that there will be more marginalised groups who may not have smartphone access (~4%) or may not have been diagnosed with HIV, and our study results may not be generalisable to them. Given this high level of smartphone ownership,[85] we are confident that the vast majority of our target population will have a smartphone. Additionally, a Spanish version of the app is not currently available. Given the need to fully develop the intervention in a culturally relevant manner for non-English speakers, we aim to translate our intervention in future iterations of this project.

In summary, the remarkable biomedical advances in HIV prevention and treatment have resulted in discussions toward ending the HIV epidemic. However, this will not happen without addressing MH and SU barriers experienced by YWH.[86] iVY will examine an innovative intervention to achieve the goal of ending the HIV epidemic. This study will provide valuable data about the characteristics of virological responders and non-responders to the intervention, individualisation of the intervention based on these variables, and linkage to MH and SU treatment services among those in need. If efficacious, in future research we will investigate the intervention's sustainability for implementation across the USA. Given the influence of the COVID-19 pandemic on MH and SU challenges,[87] the use of video-counselling and provision of remote research and services will remain high.[88 89] iVY has the potential to impact HIV health outcomes and MH and SU among YWH who are disproportionately impacted by HIV and at elevated risk for poor health outcomes.

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Contributors MCDS was the lead author of the manuscript with support and input from the study principal investigator, PS. CLM, CB and VG are developing and implementing the counselling intervention. KM, LS and DW are study coordinators. AS-C is overseeing work at AIDS Healthcare Foundation. BC is providing expertise on adaptive treatment strategies. TBN is providing mentorship on statistical methods and MOJ is providing mentorship and technical expertise on intervention development and testing. All coauthors reviewed and approved the manuscript and are involved in study implementation.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

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