WYZ Study Protocol

Study Title: A Mobile Health Application for Engagement in Care Among Youth Living With HIV
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Contents

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Background

Globally, youth and young adults are recognized as being particularly vulnerable to HIV and bear a disproportionate share of the HIV burden, with HIV being the second leading cause of death.1 In the USA, youth and young adults living with HIV (YLWH) have the lowest likelihood of linking to care, being retained in care, adhering to antiretroviral therapy (ART) and achieving viral suppression, compared with other age groups.[2–4] One review estimated that among all YLWH in the USA, fewer than 6% are virally suppressed.[5] The personal and public health consequences of suboptimal adherence among YLWH include poor health outcomes, increased drug resistance, reduced efficacy of existing treatment options, widening health disparities and potential transmission of drug-resistant virus. Efforts to adapt healthcare services for YLWH are critical, lest we risk a future generation of adults who are more susceptible to developing AIDS. While barriers to engagement in HIV care and ART adherence are generally similar across settings and populations, YLWH are more likely to report barriers such as forgetting, being away from home, change in daily routine, depression and alcohol and substance use compared with other age groups.[6] Additionally, studies have shown that YLWH face many challenges across the HIV care continuum, and clinical outcomes are worse in this group compared with adults.[7] The combination of these health disparities and developmental challenges in this transitional period may further hinder YLWH's ability to maintain optimal ART adherence and sustain virological suppression.[1 7] The link between younger age and lower ART adherence and higher risk of

virological failure has been reported in numerous studies.[8–11] However, there are few studies to inform the design of youth-friendly healthcare services and interventions.[12]

The widespread use of personal mobile phones presents an opportunity to develop novel interventions capable of bridging structural and systemic gaps in service and improving the equity of healthcare delivery. Mobile health (mHealth), the use of mobile technology for health, has the potential to reduce barriers to healthcare access, increase use of healthcare services and improve health outcomes among underserved populations.[13] Reducing barriers like travel to healthcare settings, mHealth interventions hold the potential to increase accessibility for underserved populations and allow for more efficient use of provider resources.[14] Additionally, technology-based interventions have the capacity to consistently deliver interventions with high fidelity and to complement and integrate with other healthcare services and technologies. As the largest consumers of mobile technology and internet use, youth and young adults hold the greatest potential to benefit from such technology-based interventions.[15] In the USA, among 18–29 year-olds, greater than 77% download mobile applications and over 90% are users of social media.[16 17]

There is a rapidly growing body of evidence demonstrating efficacy of mHealth interventions among various populations and for a variety of conditions, yet the field is nascent and confronting challenges related to limited generalisability,[18] lack of rigorous long-term evaluations and demonstration projects,[13] and complexities in evaluating efficacious theory-driven components.[19] The purpose of our research is to build on our theory-guided model and formative research to develop an mHealth application called WYZ for improved engagement in HIV care and ART adherence, and pilot test it among 18–29 year-olds living with HIV.

Objectives

WYZ is an mHealth intervention designed and developed in collaboration with YLWH to improve ART adherence and engagement in HIV care among this age group. WYZ contains three main features, My Health, My Team, and My Community. My Health allows users to keep track of their ART medication information, visualize their adherence and laboratory data, and understand their health; My Team provides community resources and facilitates communication with health care team members; and My Community allows for social support from peers through anonymous and moderated discussion forums and allows users to stay up-to-date on health-related news. These features were developed with guidance from youth and young adults living with HIV and further refined through focus groups with youth and young adults living with HIV and iterative field testing with our Youth Advisory Panel (YAP), and were chosen to address specific barriers to ART adherence and engagement in HIV care (e.g., social isolation and lack of community support).

We will conduct a 6-month single-arm pilot study to examine WYZ feasibility and acceptability among YLWH (18–29 years old) who live or receive care in the San Francisco Bay Area. The objective of this forthcoming phase is to refine the design and development and pilot test WYZ.

All study activities, including recruitment, screening, enrolment, study assessments, provision of incentives and exit interviews, will be conducted remotely.

Sample Size and Eligibility

We will enroll up to 10 health care providers and up to 85 YLWH study participants. Of these 85, we will select a subset of 25 participants to take part in a 30 minute qualitative interview about their experience with the app.

Inclusion Criteria:
1. All YLWH will be confirmed HIV-positive, age 18-29, be able to speak and read in English, have a smartphone (iOS V10.0 and above or Android V5.0 and above), and be able to understand the consent procedure and voluntarily sign consent forms.
2. Health care providers are primary care providers, nurses, social workers and pharmacists who provide care to participating individuals.

Exclusion Criteria:
Those with evidence of severe cognitive impairment or active psychosis that impedes their ability to provide informed consent will be excluded.

Recruitment

A combination of recruitment strategies will be used to help achieve the study's enrolment goals. These include strategies such as posting flyers at clinics and community-based organizations, participant submission of contact information through the study website (wyz.ucsf.edu) and contacting healthcare team members to refer application users. We will also work with a city-wide consortium of youth service providers and the CAPS Youth Advisory Panel to disseminate study information to the target population. Enrolled participants will be encouraged to refer eligible peers and receive $10 incentive for the referee and the referred individual who participates. Lastly, participants from the principal investigator's prior studies who had expressed interest and consented to be contacted about future research will be given the opportunity to participate, if still eligible.

Procedures

Eligibility screening

Interested individuals will be provided a brief overview of the study goals and given the chance to ask questions. Individuals wishing to enroll in the study will be screened for eligibility. To confirm an individual's age, we will require a photo identification showing their date of birth. To confirm an individual's HIV serostatus, we will require a clinician's letter of HIV diagnosis, copy of laboratory test results (for HIV antibody or HIV viral load), or the individual's ART prescription showing their name. These documents can be sent as a text message to the encrypted and secure study phone for verification by study staff.

Consent and enrollment

To enroll in the study, individuals will review and sign an electronic consent form sent to them via Qualtrics (Provo, UT, USA; version March 2017). All participants will be emailed a copy of the Experimental Subject's Bill of Rights as mandated by the State of California and a signed copy of their consent. If a participant does not have an email address, the study staff will assist them in signing up for one, as it will be necessary for gaining access to WYZ.

Participant retention

A number of steps will be taken to engage and retain participants throughout the study period. First, participants will be asked for multiple forms of contact information (including emergency contacts, clinical contacts and social media contacts) at the initial visit. They will receive monthly follow-up text messages to confirm that their contact information has not changed. Finally, participants will receive reminder text messages 24 hours before scheduled study activities.

Participant incentives

Participants can receive up to a total of $215 incentive for completing all study activities. They will receive $40 for the baseline session, which includes consent, application installation and baseline survey. They will then receive $10, $10, $15, $15, $20, $20 and $25 for participating in check-ins at weeks 1, 2, 4, 8, 12, 16 and 20, respectively. For the final exit survey at week 24, participants will receive $40, and those who are invited to participate in the exit qualitative interview at this time will receive an additional $20. Part of this incentive is aimed at offsetting any data and text messaging fees associated with the application use. We estimate that participants will spend a total of 4–4.5 hours for study activities. Participants will be given a ClinCard, a reloadable debit card, which will be used for the remote provision of study incentives. Finally, we will offer $50 to each healthcare provider for participating in a one-time qualitative interview.

Outcome Measures

The main outcomes of the pilot trial include feasibility and acceptability as indicated by meeting or exceeding the benchmarks presented in table 1. Feasibility will be assessed via user metrics by examining the participant's interactions with WYZ via a mobile analytics service called Flurry and backend (Salesforce) reporting tools (table 1). Acceptability will be examined during monthly check-ins to examine satisfaction with application use, the system usability scale (SUS),[20] a study-developed acceptability survey and an exit qualitative interview. HIV viral load and CD4+ cell count will be collected to determine feasibility of collecting these measures at both baseline and study completion.

Table 1
Feasibility metrics and threshold for determining feasibility

Measure	Threshold (per user)
General	
Recruitment	Recruit at least 55 participants (i.e., 70% of target n)
Number of log-ins	Mean of 1 log-in per week

Mean number of minutes in application	Mean of 15 min in application per week
My Health	
Use of refill feature	Use of feature once monthly (if receiving 30-day ART supply)
Use of ART adherence tracking	Track meds at least three times per week
Access of laboratory data	Review of laboratory data at least one time per month
My Team	
Communications with clinical team member	Mean of one communication per month with clinical team member
My Community	
Postchat or response to chats	Mean of one post or response to a post per week
Calendar and news	Minimum access once per week
Administrative	
Time for participant onboarding	Mean of 30 min to onboard (including downloading app and reviewing app features)
Time to maintain and support application	<1 hour per participant per week (excludes first visit)
Mean number of app crashes reported	Fewer than one self-reported app crash per week

Given that application use engagement is a complex and multifactorial concept, we aim to move beyond simple metrics. Therefore, in addition to feasibility measures detailed in table 1, we will examine an engagement index (EI) that has been detailed in other mHealth interventions.[21] The EI includes the following subindices: (1) click depth (number of pages a user views per session), (2) loyalty (measures how frequently users access the application during the study period), (3) recency (the time difference between each session the user accessed the application), (4) interaction (number of push notifications opened from those sent through the application), and (5) feedback (subjective measure of participants' satisfaction with the application).

Data Analysis Plan

We have established minimum thresholds for determining the feasibility and acceptability of the intervention. Table 1 details these thresholds for the feasibility metrics. For acceptability, SUS scores range from 0 to 100 and scores >68 are considered above average. We will use a threshold of 70% or greater satisfaction to determine acceptability. Means and proportions will be computed at the study endpoint to enable descriptive evaluation of feasibility and acceptability. For EI, we will add all five subindices and examine cut-off points based on the distribution of the total samples' EI scores and categorize participants as either poorly, moderately or highly engaged.

On completion of the study, up to 20 participants will be invited to complete a one-time, audio-recorded semistructured qualitative exit interview with study staff by phone to further assess the acceptability of WYZ. We will select participants based on their EI category (i.e., poor, moderate or high engagement), and interviews will occur until data saturation or until 20 participants have been interviewed. The interviews will focus on the participant's (1) attitudes towards exiting features; (2) attitudes and perceptions of privacy and information security; (3) features that they would modify, add or eliminate; and (4) suggested modifications to increase engagement and sustained use of WYZ.

Finally, we will conduct in-depth qualitative interviews with clinical team members whose patients participated in the pilot study. The interview will focus on perceived (1) burden or ease of study procedures; (2) attitudes and beliefs regarding impact of the intervention on users' engagement in HIV care and ART adherence; (3) sustainability and scalability of the application to other youth in the clinic; (4) challenges of integrating an application into clinical work; and (5) suggested modifications to improve usability. All interviews will be done by phone, digitally recorded, transcribed verbatim and deidentified. Transcriptions will be analyzed using thematic and content analysis frameworks. This combination is useful in identifying implicit and explicit ideas within the data while also allowing for quantification of qualitative data.[22]

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