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ORIGINAL PAPER

VITAL Start: Video-Based Intervention to Inspire Treatment Adherence for Life—Pilot of a Novel Video-Based Approach to HIV Counseling for Pregnant Women Living with HIV

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Abstract

We developed and piloted a video-based intervention targeting HIV-positive pregnant women to optimize antiretroviral therapy (ART) retention and adherence by providing a VITAL Start (Video-intervention to Inspire Treatment Adherence for Life) before ART. VITAL Start (VS) was grounded in behavior-determinant models and developed through an iterative multi-stakeholder process. Of 306 pregnant women eligible for ART, 160 were randomized to standard of care (SOC), 146 to VS and followed for one-month. Of those assigned to VS, 100% completed video-viewing; 96.5% reported they would recommend VS. Of 11 health workers interviewed, 82% preferred VS over SOC; 91% found VS more time-efficient. Compared to SOC, VS group had greater change in HIV/ART knowledge ($p < 0.01$), trend towards being more likely to start ART ($p = 0.07$), and better self-reported adherence ($p = 0.02$). There were no significant group differences in 1-month retention and pharmacy pill count. VITAL Start was highly acceptable, feasible, with promising benefits to ART adherence.

Keywords HIV · ART · Adherence · Retention · Video · Counseling · Malawi

Introduction

Remarkable global efforts have led to unprecedented access to lifesaving antiretroviral therapy (ART). Currently more than half of those living with HIV—approximately 19 million people—are now on ART [1]. Recently, a significant contributor to this milestone has been the implementation of the universal lifelong test and treat ART strategy. In 2011, Malawi successfully pioneered the first application of this strategy, Option B+ (B+). The B+ program provides free lifelong ART for all pregnant and breastfeeding women living with HIV. The proportion of women receiving ART for prevention of mother-to-child transmission (PMTCT) increased from 20% in 2009 to 84% in 2016 [2], and rates of vertical transmission declined [3]. B+ is now standard of care for PMTCT in most high HIV prevalence countries [4].

However, there is growing concern that suboptimal retention and ART adherence may undercut these gains [5, 6]. Patient adherence is necessary to achieve viral suppression- the ultimate goal of ART that confers maximal health benefits and reduced transmission risk [7, 8]. In Malawi, women who initiated ART under B+ were five times less likely to return to clinic after the first visit than those who initiated for their own health [9]. Only 59% were retained through two years and of these only two-thirds achieved adherence rates of at least 90% as measured by pharmacy refill data. The majority of loss to follow-up (LTFU) occurred within the first three months

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of ART initiation. Among those LTFU, half were lost after their ART initiation visit, failing to return for their very first follow-up [10]. This issue is not unique to Malawi, as evidence from other B+ countries demonstrates shortfalls in adherence and retention after scale up of B+, with the most significant drop in retention occurring before the first follow-up visit [11–16].

Reasons for these challenges are multifactorial, but an important contributor is that rapid ART expansion has occurred with minimal increases in the health workforce. Overextended staff have had to absorb a new flood of patients, resulting in suboptimal pre-ART education, long wait times, increased health care worker (HCW) burnout, and frustrating provider-patient interactions [10, 17–20].

Efforts to improve retention and adherence have identified supporter interventions—community health workers or other peers—as the most effective intervention, however these gains thus far have been modest, and require sustained human resource and financial inputs [21, 22]. Given that the majority of LTFU seems to be occurring early, before the first follow-up visit, intervening at the very first ART initiation visit is a critical opportunity to successfully engage women in care. To avoid losing the gains made in increasing ART coverage, an effective, low-cost intervention targeting the first ART initiation visit that can be easily scaled up within rapidly expanding ART programs is urgently needed.

Brief video-based interventions are a promising but underutilized tool. They are highly cost-effective [23] and have demonstrated efficacy in improving partner disclosure [24] and medication adherence [25] along with behavior and knowledge change around HIV and other sexually transmitted diseases [26–28].

Core messages can be pre-tested and standardized to maximize learning, and are effective across patient literacy levels [29]. Interventions do not require additional hiring of staff, rather they can help liberate HCW time by automating components of health education. Despite numerous advantages that make video-based interventions well-suited to busy, low-resourced, high-volume settings, very little evidence exists in the published literature describing the use of these interventions in the context of ART service delivery in Sub-Saharan Africa.

Here we review the development and preliminary results of VITAL Start, a standardized ART educational video-based intervention provided to HIV-positive pregnant women. Based on three behavior-determinant models, this intervention aims to promote behavioral change in maternal retention and adherence by providing a VITAL Start (Video intervention to Inspire Treatment Adherence for Life) at the critical teachable moment before committing to lifelong ART. We describe VITAL Start's acceptability and feasibility along with its impact on patient knowledge, adherence self-efficacy, adherence, and retention.

Methods

Intervention Development

The video intervention was developed through a community participatory approach, which is implicitly collaborative and designed to promote connections between the individuals, communities, and organizations involved [30, 31]. The community participatory approach was guided by the Theory of Reasoned Action, which is based upon the idea that behaviors are guided by attitudes, beliefs, experiences, and expectations of other people's reactions.

The VS development process was iterative and multistep involving a team of persons living with HIV, researchers, clinicians, Malawi Ministry of Health (MOH) staff, and other stakeholders. It was modeled on the Centers for Disease Control and Prevention funded "Video Opportunities for Innovative Condom Education and Safer Sex" (VOICES) intervention. VOICES is a group-level, single-session video-based intervention that has demonstrated success in improving knowledge around sexually transmitted infections (STIs) and reducing rates of HIV transmission, with a durable effect under real-world conditions [27, 28]. VOICES was also identified as a model due to its culturally specific content aimed at single-sex audiences, and its interactive component that occurs after viewing. We convened an advisory group of community health care workers, ART providers, and Malawi MOH officials who assisted with all aspects of conceptual and video development (Fig. 1).

Identification of a Theoretical Framework

Three behavior-determinant models were selected based on their ability to effectively promote behavior change in HIV/STI interventions. These models were social cognitive theory to address social influences, [32] the theory of planned behavior to address the cognitive aspects of how patients may conceptualize health threats and appraise barriers to or facilitators of lifelong retention and adherence to ART [33], and the information-motivation-behavioral (IMB) skills model [34]. The IMB model was the central guiding model; it asserts that knowledge alone is insufficient for behavior change, and must be linked to both motivation and behavioral skills to overcome barriers critical to achieving adherence. VS includes all components of the IMB model, and integrates other evidence-based video techniques to promote behavior change such as video modeling (active and visual demonstrations of desired behaviors) and gain-framed messaging (Table 1). Gain-framed messaging—where the advantages of behavior change are

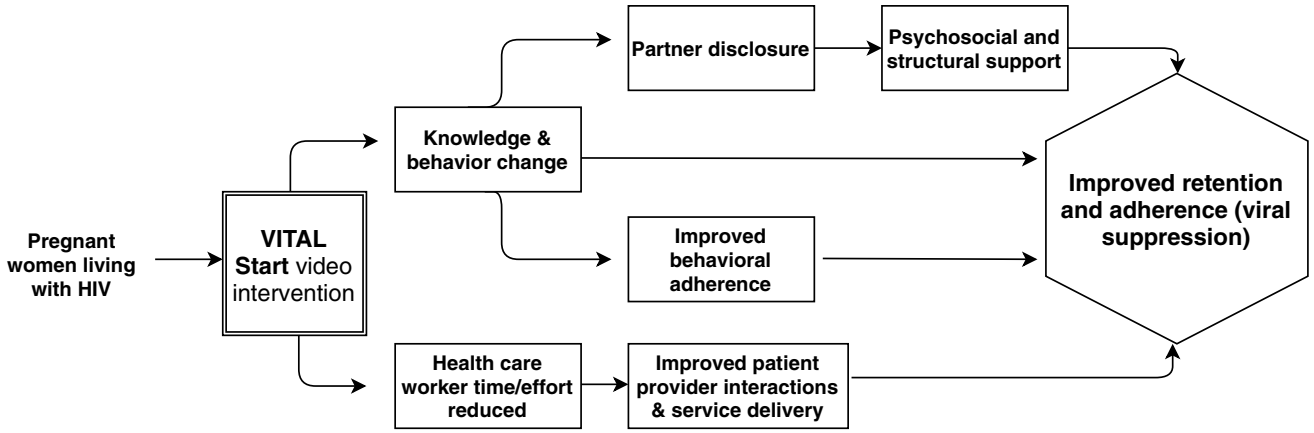

Fig. 1 Hypothesized causal pathway by which VITAL Start may improve maternal retention and ART adherence

Table 1 VITAL Start content mapped to the Information Motivation Behavioral concept framework

Component	Video content (27 min)	Post-video counseling content (8 min)
Information	Information about how HIV and ART affect the body, side effect management, importance of adherence for limiting resistance, and adherence strategies	Reiterates key messages using pictures and text
	Addresses common misconceptions about ART	Question and answer session highlight key points
Motivation	Gain-framed messaging positively frames lifelong adherence for benefit of mother, partners, and infant to increase adherence motivation	Prompts discussion around personal hesitations/concerns to build confidence
	Protagonist expresses common concerns about ART and models autonomy and adherence self-efficacy	Prompts discussion on enhancing social support network
	Positively frames autonomy to facilitate partner disclosure and to seek social support	
Behavioral	Protagonist models integrating ART into daily life by taking prescribed dose at scheduled time	Promotes problem solving to identify *adherence barriers and develop solutions,* integrate ART into daily routine, manage side effects, and handle common situations that affect retention/adherence
	HCW addresses how to handle ART side effects	

emphasized, rather than the disadvantages of not changing behavior—was selected to promote adherence due to its demonstrated superiority over loss-framed messaging [35].

Content Development

Several sources were used to guide content development. Focus group discussions were conducted to gain an understanding of motivations for behavior change and included an exploration of decision making perspectives with persons living with HIV (PLHIV), members of HIV support groups, Malawi Ministry of Health clinical staff, HIV counselors, and researchers. Recent qualitative research in Malawi also guided these efforts, including in-depth interviews with women who had been lost to follow-up and women who had been retained on ART under B+ [36]. Upon reviewing these data sources, the advisory group identified three key areas that the intervention should target: (1) the importance of starting lifelong ART while feeling otherwise healthy; (2) the management of ART side effects, particularly early efavirenz-related side effects; and (3) partner disclosure. Other important subjects that were identified included basic knowledge of how resistance develops, medications that HIV-exposed infants need, and the testing schedule for these infants. The script underwent iterative review and editing by the advisory committee and scriptwriter, until the committee felt the script addressed these issues in a compelling fashion.

The end result is a film, titled Chiyembekezo ('Hope' in the local Chichewa language). It depicts an urban Malawi setting with a female protagonist, Alinafe, who is pregnant and newly diagnosed with HIV during her antenatal care. The film portrays her anxieties about her health, protecting her baby, disclosing to her husband, and remaining on ART for life. A nurse and close friend encourage her to disclose her status and remain adherent to ART, and through their reassurance Alinafe is empowered in her relationship

with her husband and prepared to take ART for life. The video content provides information about HIV treatment and prevention, models positive attitudes about lifelong ART, utilizes gain-framed messaging for partner disclosure and engagement, and provides education on infant HIV testing and treatment.

Videotape Production

Original content was created and refined through a partnership with In Tune For Life, a non-profit organization that aims to provide creative media solutions to improve health in local communities. Local Malawian actors were cast through open auditions. We filmed on-site in Lilongwe, Malawi, specifically in nearby residential communities and at a widely-used MOH facility. Actors spoke in Chichewa, the most commonly used language in Malawi. Special emphasis was placed on including shots of recognizable landmarks and everyday urban life in Malawi. Local Malawian music was incorporated throughout the film. The finalized videotape was 27 min long, and intended to be followed by 8 min of interactive question and answer with a HCW, for a total intervention time of 35 min.

Preparation for Viewing

Portable electronic tablets were used for clinic-based video viewing. These were chosen for the following reasons: (1) extended battery life, allowing uninterrupted viewing during power outages that are routine in our setting; (2) durability; (3) security, including both physical (through a security cable) and electronic (by restricting access to unauthorized applications); (4) sufficient audio quality to ensure video could be heard in busy clinics; and (5) low cost to ensure scalability.

VITAL Start Pilot Study

Our pilot aimed to evaluate VITAL Start's acceptability, feasibility, and impact on short-term knowledge and psychosocial (adherence self-efficacy) as well as behavioral outcomes (partner disclosure, retention, behavioral adherence).

Setting

Malawi is a country of 19.1 million people in southern Africa. Life expectancy is 64 years, per capita GDP is $300 USD, and the adult literacy rate is 66% [37]. Adult HIV prevalence is 10.6% [38]. Over 95% of pregnant women attend antenatal clinic (ANC) at least once with HIV status ascertained in over 80% [39]. We conducted the pilot at three government health facilities in central and southeastern Malawi that were representative of the type of health facility in which VS could be scaled up. Specifically, they had: (1) high antenatal HIV prevalence ranging from 9 to 12.4% [39], (2) high patient volumes (> 50 patients seen at ANC), (3) represented both urban (two facilities) and rural (one facility, (4) provided free HIV testing and ART according to Malawi MOH guidelines. A fixed-dose combination pill containing tenofovir, lamivudine, and efavirenz is the first line regimen for all adults newly initiating ART, including pregnant women.

Preparation for Pilot

We provided a 3-h training to 11 health care workers (HCWs). HCWs learned to deliver the intervention effectively and reported confidence in operating the tablet. HCWs were required to pass a practical exam that evaluated their ability to properly administer the intervention. Private viewing areas that were convenient to overall clinic flow were identified and reserved. Tablets were procured and equipped with a hard cover that also served as a viewing stand, a security cable, and special software to prevent the use of other applications and to track the device in case of theft.

Patient Recruitment and Intervention Delivery

HIV-positive pregnant women not on ART who presented for antenatal care between December 2016 and February 2018 were eligible for recruitment. Other eligibility criteria included age greater than 18 or greater than 16 who were either married or had a previous child; understands Chichewa; no disabilities that would prevent them from viewing or understanding the video; and residence in the health center catchment area for 12 months. Women identified as eligible were referred to trained research assistants (RA), who provided information regarding the study. Informed, written consent was obtained from all willing participants. Following consent, participants were randomized 1:1 to receive either VS or SOC counseling.

There were a total of 26,647 total visits to ANC. Of the 520 women identified as living with HIV and not on ART, 434 (84%) were screened for eligibility, 343 (79%) were eligible, and 306 (89%) of those eligible consented and enrolled in the study; 146 were randomized to receive VS and 160 SOC.

SOC consisted of a health care worker delivered lecture style counseling session based on the Malawi National pre-ART counseling flipchart [40]. Topics included information on the basics of HIV/AIDS, PMTCT, and the importance of ART adherence. SOC typically takes about 1 h. Participants assigned to VS did not receive the SOC. Instead, for those receiving the intervention (VS), a trained HCW prepared the video for viewing, and afterwards engaged patients in an 8-min interactive question and answer session based

on core messages in the film. The video contained all key topics that would typically be covered in the didactic SOC Malawi National pre-ART training but were delivered via a dramatized video format (noted above under *intervention development*).

Data Collection

Trained RAs administered baseline and 1-month follow-up questionnaires. The questionnaires were translated into Chichewa and back-translated to English. Items were pre-tested with potential participants to ensure understanding and correspondence with the local language and culture. All participants were issued a study ID number to facilitate follow-up. A study staff member, who was experienced in qualitative interviewing in this context, conducted one focus group discussion (FGD) and 26 one-on-one semi-structured interviews with VITAL Start recipients; the main objective was to understand women's views on the content, delivery, and application of messages in the video. The RA recruited participants. Women were conveniently sampled until data saturation. Clinic retention data was extracted from patient medical records.

Measures

Demographic, Background, Medical Characteristics, and Psychosocial Functioning These included age, education, employment, monthly income, literacy, marital status, and gestational age. Data specific to HIV status included date of HIV diagnosis and ART start. Locally validated versions of the following tools were used to assess: depression (World Health Organization [WHO] self-reporting questionnaire [SRQ]) [41]; social support (multi-dimensional scale of perceived social support [MSPSS]) [42]; WHO intimate partner violence (IPV) tool [43]; alcohol use (alcohol use disorders identification test [AUDIT]) [44] and drug use (drug use disorders identification test [DUDIT]) [45].

WHO SRQ had binary responses (Yes/No) for a total of 20 items. Cutoffs of 4 and 8 were used to classify level of depression into three categories (Low, Medium and High) [46]. MSPSS was scored on a 5-point scale (1–5) for a total of 12 items and had three sub-categories that included significant other, family and friends. Total score ranged between 5 and 60 (sub-category score ranges between 5 and 20) with a higher score indicating a higher level of perceived social support. Total scores were calculated from all completed items as well as the sub-categories [47]. IPV had binary responses (Yes/No) for a total of 13 items that assessed ever having experienced sexual, emotional, or physical violence. Any 'Yes' response was classified as 'yes' for IPV. The AUDIT had 10 items. A higher score indicated more problematic use of alcohol. A score of 3 or greater was classified as harmful drinking [48]. The DUDIT had 11 items. A higher score indicated more problematic use of drug. A score of 2 or greater was classified as a drug related problem [49]. For both AUDIT and DUDIT, those with missing responses in item one, or reported as an alcohol/drug user but with missing responses on all items were treated as missing data.

Acceptability and Feasibility

We assessed patient acceptability and feasibility (comfort with tablet and patient satisfaction) using two tools. Comfort with tablet was assessed using a single item, "How comfortable would/did you feel watching a video on a tablet or mobile device?", asked immediately before and after the intervention. Response options were comprised of a three-point Likert scale 'Not comfortable at all' to 'Very comfortable'. Patient satisfaction was assessed with nine questions scored on a five-point scale (1–5) with a single item score of 5 and a total score of 45 indicating the highest level of satisfaction [27]. Of the nine items, items 8 and 9 [50] were introduced later, thus not all participants completed those items. Therefore, two versions of total score for patient satisfaction were derived: one for completing items 1 to 7, and another for all 9 items. Exemplar satisfaction questions included "I could see myself applying some of the techniques in the counselling session to my life", and "I would recommend this type of education/counselling to others in my situation".

All 11 HCWs involved in the pilot were administered a feasibility/acceptability questionnaire comprised of 12 open- and close-ended statements assessing the comfort with and quality of the tools provided to conduct the counseling session, and the session's effectiveness at providing information. The same questionnaire was administered twice to each HCW, once for SOC and once for VS. Response options used a five-point Likert scale from "Strongly disagree" to "Strongly agree". An additional seven open- and close-ended items assessed the HCWs preference between VS and SOC counseling sessions in terms of time taken, ease, and general partiality. All tools were adapted from video-based satisfaction surveys.

Changes in Knowledge and Psychosocial Outcomes

We assessed the impact of the intervention on the hypothesized causal pathway that knowledge acquisition and psychosocial changes will lead to adherence and retention behavior change.

Knowledge was assessed using 13 true/false/don't know items. Six items were taken from an instrument used in a similar study, the Maternal Child Health-ART HIV/AIDS Treatment Knowledge Inventory (v2.1), [51] and language was adapted following pilot testing to ensure clarity

and local terminology. For example, we changed the term 'antiretroviral medications' to 'ARVs,' a more commonly used phrase identified through pilot testing, and 'on schedule' to 'as prescribed' to clarify it constituted both timing and dosing of medication. The remaining items were developed using pertinent patient information regarding viral load and PMTCT from Malawi Ministry of Health guidelines. Knowledge categories included: PMTCT, viral load, ART (resistance, side effects, ART for life), and infant HIV treatment.

Patients' perceived self-efficacy was measured using an adapted version of the validated HIV-Adherence Self Efficacy tool [52]. Adaptions included: (1) changing the term 'treatment plan' to ARVs; (2) removal of the items "continue with the treatment plan your physician prescribed even if your T-cells drop significantly in the next 3 months?" and "Stick to your treatment schedule when it means changing your eating habits?" as they did not pertain to current Malawi Ministry of Health guidelines; (3) addition of an item regarding PMTCT ("that taking ARVs is helping to protect your infant from HIV"); and (4) changing the response scale to a four-point Likert scale ranging from "Not sure" to "Extremely sure" that has been used and well-received in similar studies. The final tool comprised of eleven items was administered immediately pre- and post-counseling session.

Behavior Outcomes

We assessed the impact of the intervention on short-term behavior outcomes including partner disclosure, retention in HIV care, and behavioral adherence (self-report and pharmacy pill count). Partner disclosure was self-reported at baseline and at the 1-month follow up. Pharmacy refill and retention data were abstracted from Ministry of Health records. Self-reported adherence was evaluated by asking participants whether or not ART doses were missed in the preceding 7 and 30 days at the 1-month follow-up visit [53].

Data Analysis

All questionnaires were entered onto an Excel spreadsheet with embedded data validations and checked for accuracy and completeness. We excluded seven subjects who were randomized but found to not be eligible for the study (either not pregnant or already on ART). A modified intent to treat (mITT) analysis was performed [54].

'Refuse to answer' responses were considered missing for SRQ, MSPSS, ASE, IPV, AUDIT and DUDIT items. Knowledge items were scored as either correct or incorrect with 'Don't know' and 'Refuse to answer' responses considered incorrect with a high score of 13, indicating all correct responses. Knowledge scores pre- and post- the counseling sessions as well as the change score (post minus pre) were calculated. Adherence self-efficacy was scored on a 4-point scale with a single item score of 4 and a total score of 44 indicating the highest level of perceived efficacy. Mean scores from 13 items pre- and post- counseling sessions as well as the change score (post minus pre) were calculated. We performed a sensitivity analysis with imputed data for missing items. For imputation, we used means calculated from the available items from the same individual from the same scale. For SRQ and ASE, we imputed from individuals that completed at least 80% of items for SRQ and ASE. For knowledge, we used data from any available items given that the missing items were due to administrative error (research staff mistakenly skipped administering questions) and were not participant response related.

Short-term retention (retention at 1-month) in ART clinic was defined as retained if there was a visit between 14 and 61 days after their ART start date. Behavioral adherence to ART was defined in two ways (1) self-reported dichotomous yes/no to the two-item adherence assessment and (2) pharmacy record pill counts. Self-reported adherence was calculated from those who returned for one-month follow-up.

For pill count we first defined the proportion of days covered (PDC) which is the ratio of the total number of pills given during the interval divided by the follow up interval [55]. The follow up interval was calculated as the duration between ART start date and the latest visit during the 14–61 day retention period. The value was capped at 1 if the PDC was greater than 1. Then we defined a categorical adherence variable using a cutoff of 0.9; those with at least 90% pills covered were considered adherent, and those with < 90% pills covered were considered not adherent; [56] those with missing pill count data were considered as a separate category (pill not given). We also derived a dichotomous variable using the same cut off for adherence among all subjects. Those who were not retained, did not start ART, or who had missing pill count data were all considered not adherent.

Descriptive statistics, such as mean, standard deviation (SD), median and interquartile range (IQR) for continuous variables, and frequency and proportion for categorical variables, were calculated by study arm. Chi-squared test was used to compare the distribution of the categorical variables (proportions) between two groups. Fisher's exact test was used for sparse cells. For continuous variables, two sample *t* test was used to compare the means between the two groups. Wilcoxon rank-sum test was applied if there was a severe violation of normality assumptions. In addition, paired t-test or Wilcoxon signed-rank test was used to compare the pre-post scores. All tests are two-sided. A p-value of 0.05 was deemed statistically significant and a p-value of 0.1 regarded as a statistical trend. All analyses were performed using SAS software (SAS Institute, Inc., Cary, North Carolina, United States).

FGDs and interviews were transcribed and translated. Two researchers utilized an inductive approach to identify major themes and assign descriptive codes to segments of the transcripts. An iterative process was used to reach consensus on the selection of quoted passages from the coded transcripts relevant to the acceptability and feasibility of the intervention.

Ethical Considerations

The National Health Sciences Research Committee (NHSRC) of Ministry of Health in Malawi and the Baylor College of Medicine Institutional Review Board in the USA approved the study protocol. We obtained written informed consent from all study participants.

Results

Participant Characteristics, Demographic, Background, Medical Characteristics, and Psychosocial Functioning

Table 2 lists the demographic, background, medical characteristics, and psychosocial functioning by study group. Mean (SD) age of study participants was 27.3 (9.1) in SOC and 27.5 (5.7) in VS. Mean gestational age (weeks at enrollment) was 20.2 (6.4) in SOC and 21.6 (6.6) in VS. Only 33.1% (SOC) and 34.3% (VS) had completed a junior education or higher (higher than standard 8 education); and 70.6% (SOC) and 72.6% (VS) were literate. The majority of women in both groups, 90.6% (SOC) and 87% (VS), were diagnosed with HIV at the time of enrollment. The only statistically significant difference between the groups was with regard to use of alcohol, with 9.4% of the control group compared to 2.7% of the intervention group being frequent users (p-value = 0.02).

Feasibility

All participants assigned to VS completed video viewing, and 91.1% reported feeling comfortable watching the video on the tablet, 122 (83.6%) very comfortable, and 11 (7.5%) somewhat comfortable. Eleven HCWs completed the feasibility and acceptability questionnaire. All HCWs reported feeling confident conducting the video intervention and 91.9% agreed that the tools provided for conducting the intervention were adequate. Compared to SOC, most HCWs found VS easier to provide (81.8%) and more time-efficient (90.9%). HCWs commented on the effectiveness of the intervention to provide information and motivation, and their own ability to address other key tasks such as preparing patient medication while participants watched the video.

> "You can do other things while the patient watches the video—like get ART and nevirapine ready."
> "Clients get information easily and are encouraged by the video message."

Acceptability

Patient satisfaction was high (Table 3) in both arms. In the VS arm, 79.3% would recommend and 17.2% would strongly recommend VS to others. Patients agreed with mean scores of ≥ 4.0 on a five-point Likert scale that the intervention helped them feel better, increased their understanding of key knowledge topics, gave examples of real-life situations, and showed techniques they could apply to their lives. There was no significant difference in satisfaction and proportion who would recommend the intervention to others in both VS and SOC arms. The majority (81.8%) of HCWs preferred VS to SOC. On a five-point Likert scale, HCWs also reported greater enjoyment in providing VS compared to SOC (4.8 vs. 3.8, p = 0.03). Participants were receptive to the intervention, and reported they were able to comfortably view the video on tablets. Analysis of interviews demonstrated that women felt encouraged to accept their HIV status and take ARVs for life as a result of VS:

> "It helped me to be courageous, when I watched that video, the way that woman accepted her status, it also helped me… It helped me to accept that I am HIV positive."

> "The video also encouraged us not to be afraid to take the medication because the way those people looked, in my view, they seemed to be young but still more she was courageous and started taking ARVs and she never stopped."

> "They encouraged us because when she knew that she was HIV positive, she didn't have those thoughts of committing suicide or of doing something bad, but instead she went to a friend whom she thought could help her on what to do, then she was helped, at the end everything turned out to be fine."

> "The video, yea it taught me something because when I watched it and then she counseled me, it encouraged me to start taking those ARVs."

> "…it gave me so much courage because I saw that I still have time, even after giving birth, if I am taking my ARVs as prescribed, if I take my ARVs at

Table 2 Participant characteristics at enrollment by study arm

Characteristic	Standard of care	VITAL Start	p-value
Age mean (SD, n)	27.3 (9.1, 156)	27.5 (5.7, 142)	0.82
Gestation (weeks at enrollment), mean (SD, n)	20.2 (6.4, 151)	21.6 (6.6, 135)	0.08
Education, n (%)			0.73
None	11 (6.9)	14 (9.6)	
Some primary school (standard 1–5)	41 (25.6)	34 (23.3)	
Primary completed (standard 6–8)	49 (30.6)	39 (26.7)	
Junior education	29 (18.1)	31 (21.2)	
Secondary education	21 (13.1)	16 (11.0)	
Post secondary education	3 (1.9)	3 (2.1)	
Refused to answer	1 (0.6)	0 (0)	
Missing	5 (3.1)	9 (6.2)	
Occupation, n (%)			0.51
Employed	11 (6.9)	13 (8.9)	
Self-employed	36 (22.5)	27 (18.5)	
Farming	13 (8.1)	17 (11.6)	
Housewife	83 (51.9)	67 (45.9)	
Not working	10 (6.3)	12 (8.2)	
Refused to answer	1 (0.6)	0 (0)	
Missing	6 (3.8)	10 (6.8)	
Monthly income, n (%)			0.16
Less than $70 USD	100 (62.5)	95 (65.1)	
Between $70 to 140 USD	33 (20.6)	19 (13.0)	
Between $140 to $350 USD	16 (10.0)	11 (7.5)	
More than $350 USD	2 (1.3)	6 (4.1)	
Refuse to answer	4 (2.5)	5 (3.4)	
Missing	5 (3.1)	10 (6.8)	
Literate, n(%)			0.90
No	43 (26.9)	36 (24.7)	
Yes	113 (70.6)	106 (72.6)	
Missing	4 (2.5)	4 (2.7)	
Relationship with partner, n(%)			0.56
No partner	14 (8.8)	13 (8.9)	
Married	131 (81.9)	115 (78.8)	
Not married, but has a steady partner	12 (7.5)	11 (7.5)	
Missing	3 (1.9)	7 (4.8)	
Time of HIV diagnosis, n (%)			0.59
Today	145 (90.6)	127 (87.0)	
Before today, but during this pregnancy	5 (3.1)	5 (3.4)	
Before today, but not during this pregnancy	4 (2.5)	5 (3.4)	
Refuse to answer	1 (0.6)	0 (0)	
Missing	5 (3.1)	9 (6.2)	
Social support scores (MSPSS: multi-dimensional scale of perceived social support), mean (SD, n)			
MSPSS total	44.6 (5.8, 151)	44.7 (6.0, 135)	0.94
MSPSS significant others subscale	15.7 (1.9, 151)	15.6 (1.9, 135)	0.41
MSPSS family subscale	14.9 (2.6, 152)	14.9 (2.6, 136)	0.97
MSPSS friends subscale	14.0 (2.8, 153)	14.2 (2.9, 135)	0.46
Depression score (World Health Organization self-reporting questionnaire), n (%)			0.92
Low (0–4)	96 (60.0)	84 (57.5)	
Medium (> 4 to < 8)	23 (14.4)	21 (14.4)	
High (8 +)	31 (19.4)	29 (19.9)	

Table 2 (continued)

Characteristic	Standard of care	VITAL Start	p-value
Missing	10 (6.2)	12 (8.2)	
Ever reported? Intimate Partner Violence (World Health Organization), n (%)			0.76
No	84 (52.5)	77 (52.7)	
Yes	55 (34.4)	46 (31.5)	
Missing	21 (13.1)	23 (15.8)	
Alcohol use, AUDIT score, n (%)			0.02
Non-drinker	132 (82.5)	122 (83.6)	
Low risk	8 (5.0)	4 (2.7)	
High risk	7 (4.4)	0 (0)	
Missing	13 (8.1)	20 (13.7)	
Drug use, DUDIT score, n (%)			
No drug related problem	139 (86.9)	125 (85.6)	0.06
Drug related problem	5 (3.1)	0 (0)	
Missing	16 (10.0)	21 (14.4)	

Table 3 Participant satisfaction, change in knowledge, adherence self-efficacy, partner disclosure, retention and adherence

Outcome	Standard of care	VITAL Start	p-value
Satisfaction score, mean (SD, n)	37.3 (3.6, 91)	36.7 (4.3, 86)	0.37
I would recommend this type of education/counselling to others in my situation, mean (SD, n)	4.1 (0.4, 91)	4.1 (0.5, 86)	0.94
Comfort with watching a video on a tablet or mobile device, n (%)			–
Very comfortable	–	122 (83.6)	
Somewhat comfortable	–	11 (7.5)	
Not comfortable	–	1 (0.7)	
Missing	–	12 (8.2)	
Change in knowledge from pre- to post intervention, mean (SD, n)	1.2 (2.1, 152)	2.0 (2.7, 137)	**0.01**
Change in adherence self-efficacy at one-month, mean (SD, n)	0.74 (5.86, 108)	1.56 (5.68, 103)	0.34
Disclosed to partner at one-month, n (%)			0.87
No	16 (10.2)	12 (8.6)	
Yes	83 (52.9)	72 (51.4)	
Already disclosed to at baseline	20 (12.7)	22 (15.7)	
Refused to answer	0 (0)	1 (0.7)	
No partner	14 (8.9)	13 (9.3)	
Missing	24 (15.3)	20 (14.3)	
Started ART, n (%)	153 (95.6)	145 (99.3)	0.07
Retained in ART clinic at one-month, n (%)	120 (75.0)	113 (77.4)	0.69
ART adherence as calculated by electronic pharmacy pill count > 90–100%, n (%)	95 (59.4)	95 (65.1)	0.31
Self-reported ART adherence at one-month, n (%)			
Missed dose in past 7 days	34 (26.8)	16 (13.6)	**0.02**
Missed dose in past 30 days	38 (29.9)	18 (15.3)	**0.02**

Bolded values represent p-values < 0.05

8 o'clock, I need to take them at 8 o'clock again, I shouldn't skip."

Knowledge, Adherence Self-Efficacy, and Behavioral Outcomes

There was a greater change in knowledge in the VS group ($p < 0.01$) with a mean (SD) increase of 2.0 (2.7) compared to SOC group 1.2 (2.1) from pre- to post- intervention (Table 3). The VS group had significant improvements in ART knowledge with and without adjusting for literacy or educational status with linear regression modelling. There was a significant change in mean (SD) ASE score from baseline [34.47 (4.93)] to 1-month follow-up [35.83 (4.85)] in only the VS group, $p = 0.02$; when comparing the change in ASE from baseline to 1-month follow-up in the VS group [1.56 (SD 5.68)] vs. the SOC group [0.74 (SD 5.86)], the change appeared to be greater in the VS group, but was not statistically significant.

There was a trend towards more women in the VS vs. SOC group, starting ART ($p = 0.07$). Self-reported adherence at 7 and 30 days was better in the VS group ($p = 0.02$ and $p = 0.02$). However, there was no significant difference in short-term retention nor adherence as measured by pharmacy pill count at one month.

Discussion

This is the first study describing the use of a novel video-based intervention for PMTCT in Sub-Saharan Africa. The primary goals of this study were to describe the systematic development of the VITAL Start intervention as well as its acceptability, feasibility, and preliminary efficacy in improving outcomes along the hypothesized causal pathway (knowledge, adherence self-efficacy, and treatment adherence).

The process of creating the intervention was methodical to ensure it was culturally sensitive, grounded in evidence-based frameworks, and could be brought to scale. It was locally developed using an iterative community participatory approach that included multiple stakeholders including pregnant women living with HIV. VS development was grounded in three evidence based behavior-determinant models. VS also incorporated evidence-based video techniques to promote behavior change, such as video modelling and gain-framed messaging. Utilization of these evidence-based techniques included visually demonstrating, through the main characters, strength and resilience in the face of real life struggles. VS was intentionally evaluated amongst patient populations and clinics that were representative of populations/clinics in which VS could be implemented in the future. Finally, and perhaps most importantly, it was designed to be an intervention that could be rapidly scaled up without requiring additional HCW time (such as SMS messaging, SOC pre-ART counseling, etc.).

The results are promising. VITAL Start was highly feasible to implement, acceptable to both patients and HCWs, and demonstrated promising impact on knowledge, ART initiation, and self-reported adherence. The majority of participants felt very comfortable (83.6%) watching the video and patient satisfaction was high, with over 95% reporting that they would recommend VS to others. HCWs found VS easier to provide (81.8%) and more time-efficient (90.9%) as compared to SOC. The majority (81.8%) of HCWs preferred VS to SOC. Participants in the VITAL Start group had significant improvements in ART knowledge both with and without adjusting for literacy or educational status. There was a significant change in mean ASE score at 1-month in only the VS group [1.56 (SD 5.68), $p < 0.01$]; this change appeared to be greater in the VS versus SOC group, but the difference was not statistically significant. There was a trend towards greater proportion of women starting ART in the VS group as compared to the control. There was also better self-reported adherence as compared to the control group.

We did not observe statistically significant differences between the groups in terms of adherence self-efficacy, pharmacy pill count, or short-term retention. In terms of adherence self-efficacy, the change in the VS group appeared to be greater than SOC and we may have been underpowered. In addition, we measured very short-term (1-month) changes. Since the intervention was very effective in improving their knowledge regarding ART, it is possible that this knowledge provided women with a more complete picture regarding the potential challenges of adherence, perhaps making them not as certain they would be able to adhere. Longer-term evidence regarding the impact of the intervention on self-efficacy, once women have time to digest the information, would be helpful. Although we did see a change in self-reported adherence, our outcome measure might have been too short term to see an impact of this change on pill count or retention. Also, there is potential for social desirability bias across arms. It is possible that there was contamination since VS was administered by HCWs who deliver services to all clinic patients including those in the control group; and both VITAL Start and SOC took place in the same clinic. Contamination could have led to an underestimation of the actual effects of the intervention; therefore, the findings may represent a conservative evaluation of the intervention. However, to reduce the contamination risk we employed strict study procedures to ensure participants did not accidentally view the video, for example video viewing took place in a different space from SOC. In addition, SOC counselling provided at the study sites was supported by non-governmental organizations (NGOs) and, therefore, likely higher quality

than that delivered at a typical MOH clinic. The impact of VITAL Start may be greater at sites without NGO support.

In conclusion, while preliminary, this pilot study provides support for the acceptability, feasibility, and potential benefits (improved knowledge and reported adherence) of a scalable intervention on ART adherence in the context of PMTCT. While the intervention displayed benefits along the causal pathway and for behavioral adherence, our other outcome measures might have been too short term to see an impact of VS on pill count or retention. VITAL Start is unique in that it does not create an additional burden on the HCW. HCWs only need minimal training (3 h) and in this study HCWs found VS was more time efficient, and preferred it to SOC. Moreover, if video counseling is successful in this context, there is great potential for its use in other aspects of HIV service delivery. The observed early benefits of the intervention provide evidence to support the further development and evaluation of the intervention as a tool to help patients and providers achieve optimal patient education and treatment adherence outcomes.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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