VITAL start: VITAL Start (Video-intervention to Inspire Treatment Adherence for Life): Brief facility-based video intervention to improve retention and adherence to ART among pregnant and breastfeeding women

Study Protocol including Statistical Analysis Plan and Consent Form

NCT03654898

March 26, 2020

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BACKGROUND AND JUSTIFICATION (RATIONALE FOR RESEARCH)

Malawi is a land-locked country located in Southern Africa, with a population of 16.7 million and ranks 173 out of 188 countries in the Human Development Index.[19] The average life expectancy is 55 years, annual per capita GNI is $315 USD, and the adult literacy rate is 61%.[20] The estimated national adult HIV prevalence in 2013 was 10.3%, with an estimated one million individuals living with HIV/AIDS.[21] The fertility rate is 5.6 births per woman and median duration of breastfeeding is 23 months.[22] Approximately 97% of pregnant women attend antenatal clinics at least once[22] and HIV status is ascertained in over 90% of attendees.[23] The B+ program was initiated in September 2011 and effectively integrated PMTCT and ART care. As per the most recent Malawi MOH ART program report there were 724 ART sites, 619 B+ (PMTCT) sites, 849,368 patients ever initiated on ART, and 585,660 (69%) retained alive on ART. [23] In April 2016, Malawi intends to recommend universal life-long ART for all HIV-positive persons irrespective of immunologic or clinical status.

Option B+, a simplified PMTCT strategy to eradicate vertical transmission

Despite a 58% decrease in pediatric infections since 2002,[24]an estimated 240,000 [210,000–280,000] children less than 15 years of age were newly infected with HIV in 2013; the vast majority in sub-Saharan Africa.[24] Option B+ is a PMTCT strategy that was created to eliminate pediatric HIV infection and recommends universal life-long ART upon diagnosis for all HIV-positive pregnant/breastfeeding women regardless of clinical or immune status. The program was designed to improve maternal health, prevent heterosexual transmission of HIV and prevent vertical transmission in an environment with a high fertility rate and subsequent pregnancies while simplifying program delivery. Malawi pioneered the B+ approach in 2011.[25] The early results have been positive and dramatic with a 7-fold increase in maternal ART uptake and decreased vertical transmission rates.[2] The WHO-endorsed B+ approach is now already being implemented in or scaled up in 22 countries.

Suboptimal maternal retention and adherence to ART- one of the most critical challenges facing PMTCT service delivery globally

In order to significantly reduce the number of new infant HIV infections, PMTCT retention rates in excess of 90% are required.[22] Unfortunately, maternal retention and adherence to ART remain suboptimal.[5] A national evaluation from Malawi demonstrated that as compared to women who initiated ART for their own health, those who started for PMTCT (B+) were five times more likely not to return to clinic [OR 5.0, 95 % confidence interval (CI) 4.2–6.1].[5] The most recent Malawi national B+ retention rates were 78%, 71%, and 67% at 6, 12, and 24 months, respectively. The majority of women lost to follow-up only experienced one visit—when they discovered their HIV-positive diagnosis—and it is likely that many never actually started ART. [5] This problem is not limited to Malawi—suboptimal maternal retention and adherence is one of the most critical challenges facing PMTCT services globally.[1,4,26] Non-adherence is a major cause of viremia that greatly increases the risk of vertical transmission. Further, viremia while on ART is the central cause of antiretroviral resistance and poor clinical outcomes. *Improving viral suppression in pregnant and post-partum women on ART will likely become one of the most important challenges to PMTCT programs globally.*

Key contributors to suboptimal retention and adherence to ART: partner involvement and inadequate education/preparation for life-long ART

A combination of structural, social, individual, and intrapersonal factors contribute to suboptimal maternal retention and adherence. As B+ is implemented across Sub Saharan Africa, hundreds of thousands of pregnant women (PW) will newly initiate life-long ART.[1] Clinic staff are already managing large numbers of patients and often do not have the time, knowledge or skills required to optimally counsel patients resulting in inadequate pre-ART education, long clinic waiting times, and frustrated provider-patient interactions.[6,7] Furthermore, at the individual level, women feel ill-prepared to commit

to life-long ART, or to disclose to and engage their partners to provide needed emotional and structural support.[8]

The WHO and PEPFAR have identified increasing partner involvement as a critical strategy for enhancing PMTCT implementation.[27,28] Partner involvement is associated with improved maternal utilization of HIV services[27,29-33] and treatment adherence,[29] while lack of partner engagement is associated with suboptimal maternal ART adherence in B+ programs.[8] Further, involving partners can lead to benefits for the partner themselves such as HIV testing and linkage to ART. Couples HTC (CHTC) has been shown to increase partner disclosure and engagement,[34] improve uptake of PMTCT services[29] and decrease vertical HIV transmission.[30,35] However, interventions shown to improve CHTC in study settings (ie. invitation letters home)[36-38] have not been effectively brought to scale. Limited evidence exists regarding other inexpensive, scalable strategies to improve partner disclosure and testing, particularly in the context of B+ expansion.

Research Gap

This evidence demonstrates that eliminating pediatric HIV will require novel, effective interventions to promote partner engagement, maternal knowledge acquisition, and behavior change to optimize maternal retention and ART adherence. These interventions must be appealing to patients, feasible, cost-effective, and easily scalable within rapidly expanding PMTCT programs to avoid decelerating B+ scale up.

Brief video-based education: an underutilized but promising medium for behavior change in the context of the HIV/AIDS epidemic in Africa

Brief video-based health interventions have demonstrated effectiveness in promoting behavior change and acquisition of health knowledge in a variety of clinical settings. Studies have demonstrated that video-based educational interventions increase knowledge about HIV and other STDs, promote partner disclosure,[9] influence attitudes supporting safer sex behaviors, and improve treatment compliance.[10-13]The use of video as an educational vehicle offers several advantages:

1. Video interventions are highly cost-effective requiring limited ongoing resources after content creation.[39] A cost-effectiveness evaluation of a video based HIV education program demonstrated an annual savings of greater than US $5million for 10,000 patients in averted HIV infections.[15,39]
2. Videos are not subject to inter-user variability. Therefore core messages can be pre-tested and standardized to maximize knowledge acquisition.[12,16]
3. Videos do not require additional hiring of staff, with only minimal training required for existing staff, and may indeed liberate HCW time for other activities thereby offering ancillary benefits to the health system.
4. Videos are well-suited for promoting health behavior change in settings with low literacy such as Malawi.[14]
5. Videos readily engage participants improving adoptability. Messages can be carefully crafted and woven into entertaining and dramatic story lines, and pre-tested to ensure cultural/linguistic sensitivity. The result is a consistently high-quality and motivating messaging.[12,16]
6. Videos can be highly effective if delivered at critical stress-inducing “teachable moments”,[12,16] such as the period after HIV diagnosis and prior to ART initiation.

Despite the numerous advantages of video-based interventions that make them well suited to busy, low-resourced high-volume clinical settings, this medium has been surprisingly underutilized in the context of the HIV/AIDS epidemic in sub-Saharan Africa. A search on PubMed on February 27, 2016 using the terms “video”, “HIV”, “Africa” with no language restrictions yielded 47 references of which only 4 described video-based interventions in sub-Saharan Africa. None of these studies were trials, and none examined the use of video in the context of PMTCT service delivery.

Receiving a new HIV diagnosis a highly stressful experience.[40] Pregnant women newly diagnosed with HIV within the B+ program also are faced with accepting the risk to their infants, committing to lifelong chemotherapy, and disclosing their status to their partners.[41] The antenatal clinic visit, therefore, represents a critical teaching opportunity to promote life-long commitment to ART by providing sensitive and consistent counseling that can inspire behavior change that helps women disclose their HIV status to their partners and make an informed decision to commit to life-long ART.

Creation of VITAL start (Video intervention to Inspire Treatment Adherence for Life)

We used a participatory approach and applied theoretical frameworks[17] and evidence-based message framing techniques[18] to create an innovative 37 minute, single session video-based intervention for HIV-positive pregnant women. Three behavior-determinant models were used to create the video: social cognitive theory, the theory of planned behavior and the information-motivation-behavioral skills model,[17] as well as gain framed messaging and video modeling.[18] The video promotes partner involvement, maternal retention, and ART adherence by providing a **VITAL start** (Video intervention to Inspire Treatment Adherence for Life) at the critical teachable moment between receiving an HIV diagnosis and committing to life-long ART. VITAL start not only helps standardize pre-ART education but also promotes behavior change using carefully crafted and pre-tested messages woven into an entertaining drama to engage the audience. VITAL start can be delivered in busy clinic settings with simple, cheap, durable tablet computers. VITAL start can help free up health care provider time, potentially making PMTCT service delivery more streamlined.

The VITAL start intervention consists of a 27-minute video followed by 10 minutes of question and answer with a HCW to reinforce key messages and provide an opening for individual counseling if needed. The intervention provides information about HIV treatment and prevention, models[18] positive attitudes about lifelong ART, utilizes gain framed messaging[18] for partner disclosure and engagement, and provides education regarding infant HIV testing and treatment. The film, named Chiyembekezo, (meaning 'Hope' in the local Malawi language-Chichewa) depicts an urban Malawi setting with a female protagonist (Alinafe) who is pregnant and is newly diagnosed with HIV. Alinafe receives a HIV positive diagnosis during her antenatal care. The film follows her as she navigates her anxieties about her health, protecting her baby, and disclosure to her husband. A nurse and close friend encourage her to disclose her status, and through their reassurance, Alinafe is empowered to disclose to her husband and chooses to take ART for life. Formative research was used to ensure a plausible story line, and the plot and characters continuously modified based on feedback to help ensure that potential viewers are entertained. The video was made with a relatively low budget, and adapted for a clinic setting.

The video was developed through an iterative multistep process involving a team of researchers, clinicians, persons living with HIV, Malawi MOH clinic staff, the Malawi MOH Health Education Unit, CHWs, other community members, and filmmakers. This collaborative formative research method facilitated the development of a video that not only delivers key HIV prevention, treatment adherence support, and partner engagement messages but also entertains audiences. The video-intervention was modeled on the CDC funded VOICES intervention. VOICES is a video-based intervention that has shown to be effective in reducing incident sexually transmitted disease (STD) infection in research settings,[10] is cost effective,[39] and has demonstrated ongoing effectiveness in real world settings across the US[42] more than a decade after first being implemented.[43]

Three behavior-determinant models provided the theoretical underpinnings for the intervention. They were selected based upon their demonstrated ability to effectively promote behavior change in HIV and STD interventions. The models address behavior change at the individual and interpersonal levels and include social cognitive theory, and the theory of planned behavior to address the cognitive

aspects of how patients may conceptualize health threats and appraise barriers to or facilitators of partner disclosure and adherence. The information-motivation-behavioral (IMB) skills model developed by Fisher and others[17] was also used to shape the film. The model assumes that individuals need to be knowledgeable about the need to start and adhere to ART before they can be expected to adopt the behaviors. In addition, individuals have to be motivated to change their behavior if they are to act on the information. That is, knowledge alone is not sufficient to lead to behavior change. Interventions based on this model have been effective in influencing behavioral change across a variety of clinical applications.[17,44-46] A strong body of evidence supports[47] the use of IMB in efforts to enhance retention in care and it has been effectively integrated into video platforms.[11,18,48] A recent systematic review examining 12 randomized controlled trials (9 amongst persons with HIV/AIDS) found that 10 of 12 behavioral interventions based on the IMB model reported significant health behavior changes at the first post-intervention assessment amongst persons with chronic illness.

The film also incorporated video modeling and gain framed messaging. A recent systematic review examining the effectiveness of video as a medium to promote health behavioral messages[18] and identified that "video modeling" (active and visual demonstrations of desired behaviors)[49] was particularly effective, especially if the video was racially, ethnically, linguistically, and/or culturally concordant with the target population.[50] We included video modeling of positive attitudes towards life-long ART and partner disclosure and used local actors/actresses in familiar typical Malawian settings. We also used gain framed messaging based on prior research that indicated that gain framed versus loss framed messaging was more persuasive in promoting health behavior change.[51] Key messaging integrated into the storyline included basic education on ART and PMTCT recommended for initiation of ART in the B+ program in Malawi.[22] We also sought to address barriers to partner disclosure and ART adherence identified in the region[6,7,52,53] including those identified through a recent qualitative study that we conducted in Malawi[41] that explored barriers and facilitators to ART adherence via in-depth interviews with women who were LTFU as well as those who remained adherent to ART within the context of B+. These topics included: (a) fears of HIV disclosure to others, most notably partners; (b) need for consistent, supportive education regarding life-long ART and associated side effects (most notably early efavirenz related side effects); (c) need for empowerment to persuade a partner to go for testing; and (d) lack of a clear understanding of how resistance develops and why one needs to take ART when healthy (e) lack of understanding of what medications the infant needs to receive, and when they need to go for diagnostic testing.

OBJECTIVES AND HYPOTHESES

At present no published clinical trial has reported the use of video-based interventions to improve HIV treatment related patient outcomes in low-resource countries. The proposed research addresses a question critical to optimize PMTCT service delivery and will also provide needed data regarding the impact of inexpensive, scalable video-based interventions in the field of HIV prevention and treatment. Our specific aims and hypotheses are:

Specific aim 1: To evaluate the effectiveness of VITAL start on improving partner outcomes (disclosure, testing, and linkage to ART), maternal retention and ART adherence via a multi-site, parallel group (n=446 each group), randomized controlled, outcome assessor blinded trial. We hypothesize that: the proportion of partners who are disclosed to, receive HIV testing, and are linked to ART will be higher in the intervention vs. control group at 3 months follow-up and; the proportion of women retained in care (**primary outcome**) and adherent to ART (self report, and undetectable viral load) at 12 months after ART initiation will be higher in the intervention vs. control group.

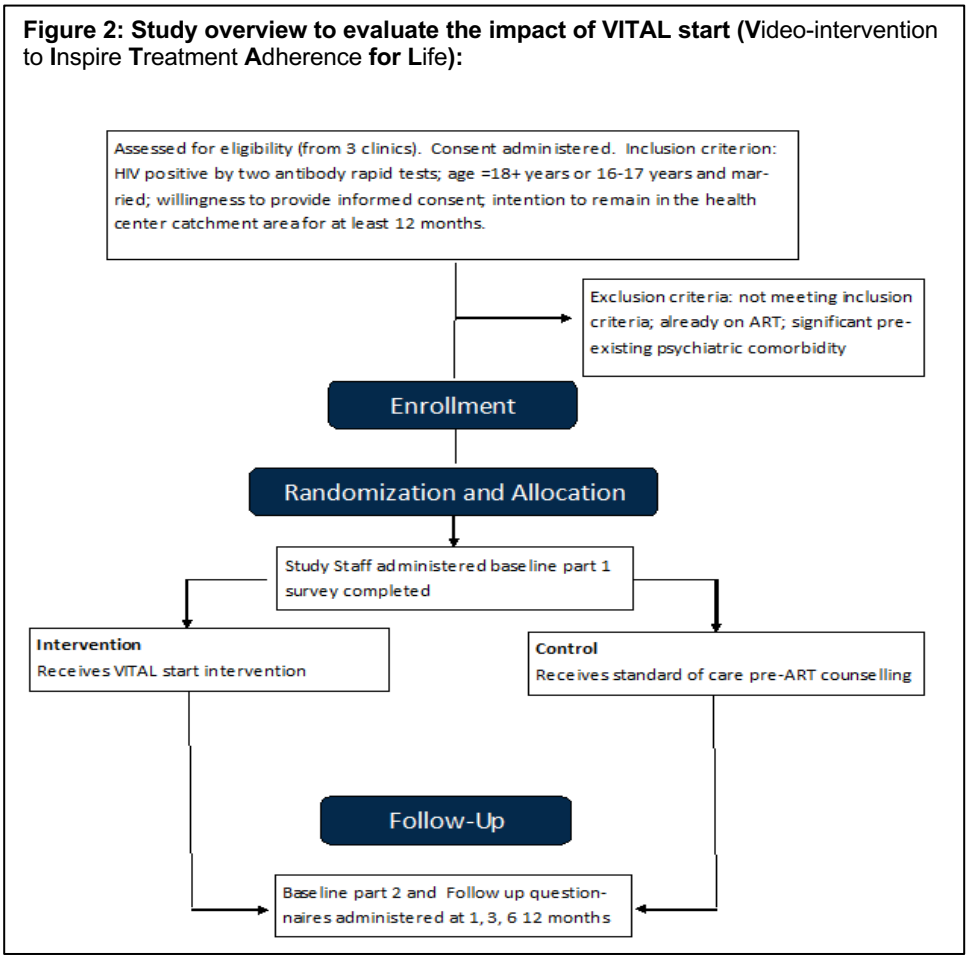
Specific aim 2: To critically examine the delivery of VITAL start via in-depth interviews and surveys administered to patients, partners, and health workers. Adoption of and satisfaction with the program will be measured. Qualitative interviews will be utilized to obtain feedback on motivational qualities of the program and benefits and challenges of delivery.

Specific aim 3: To assess the cost-effectiveness of the VITAL start intervention. Cost-effectiveness will be assessed using incremental cost-effectiveness ratios, with health effects expressed in terms of viral load suppression and costs of resources used for the intervention.

METHODOLOGY

Study Design: We will conduct a multi-center, parallel group, randomized controlled outcome assessor blinded trial with a qualitative descriptive component to assess the impact of VITAL start on partner disclosure, partner HIV testing, linkage to ART, and maternal retention and adherence to ART. We adhered to CONSORT guidelines in the design of the study[54] and the SPIRIT guidelines and checklist[55,56] for describing the details of the intervention. In brief, pregnant HIV-positive women presenting at antenatal care clinics will be randomized to receive a brief video-based intervention (**VITAL start**) or standard of care (control). The intervention group will receive the VITAL start intervention. The control group will receive standard of care pre-ART education using the national MOH flipchart. Outcomes for all participants will be assessed by blinded assessors at 1-month, 3-month, 6-month and 12–month follow-ups. A schematic of the groups and a study diagram according to the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) is shown in Figure 2.

Figure 2: Study overview to evaluate the impact of VITAL start (Video-intervention to **I**nspire **T**reatment **A**dherence **for L**ife**):**



Study Clinics: Study sites will be the following Malawi MOH facilities supported by the Baylor-Tingathe PMTCT program: Kawale Health Centre, Area 25 Health Centre, and Mangochi District Hospital. The ANC HIV prevalence of these clinics ranges from 9-15% (Table 1). In 2015, 1542 HIV-positive pregnant women attended at ANC, and of these 901 were not yet on ART. We therefore estimate that there will be >1000 HIV-positive pregnant women not on ART and eligible to be enrolled in the study during the enrollment period. Six-month retention at these high burden facilities ranges from 68-80%. Option B+ PMTCT services are provided by the Ministry of Health free of charge (Table

2). Additional Baylor-Tingathe sites may be included if necessary to maintain adequate enrollment within the specified time period.

Table 1. ANC HIV prevalence, Numbers infected and % infected women on ART at study clinics							
Clinic Name		**ANC HIV Prevalence[1]**	**HIV positive women annually**	**% HIV positive already on ART**	**Number not on ART (eligible for enrolment)**	**% retained 6months, Option B+**	**% retained, 12 months, Option B+**
Kawale	Urban	12.43%†	491†	39% (191)†	300	68% (256/377)‡	57% (230/406)‡
Mangochi DH	Rural	12.00%	603	48%(288)	315	46% (51/112)	53% (64/121)
Salima DH	Rural	15.05%*	628*	61%(382)*	246	80% (215/269)	73% (197/269)
Area 25*	Urban	11.15%	584	52% (303)	281	62% (249/401)"	58% (206/385)"

All data from Malawi MOH HIV Unit quantitative data reports calendar year 2015 unless noted otherwise
1.Using: ((new positive + previous positive) / (new positive + previous positive + new negative))*100
¶ Using data from Dec 2014 to compensate for missing data in Jul 2015
*Using data from first six months of 2015 multiplied by 2. Missing data for second half of 2015
†Using data from 2014-Q4 to compensate for missing data in 2015-Q1

‡ Using data from 2014-Q3 to compensate for missing data in 2015-Q1
*Using Q1 2016, Q3-Q4 2016 and Q1 2017
"Using Q1 – Q4 2016 for survival data

Study population: HIV-positive pregnant women presenting to ANC for enrollment into B+.

Inclusion Criteria: HIV positive by two antibody rapid tests approved by the Malawi Ministry of Health; age 18 years or older, or 16-17 years if married or have a child; willingness to provide informed consent; intention to remain in the health center catchment area for at least 6 months.

Table 2. Option B+ Services Routinely Provided at Ministry of Health Study Sites	
HIV testing	Pre-test group counseling Opt out HIV antibody testing at antenatal clinic Voluntary counseling and testing Post-test counseling session Pre-ARV counseling
Maternal ART and follow up	Once daily fixed dose tenofovir-lamivudine-efavirenz ***for life*** offered at the time of HIV diagnosis. *ART counseling Cotrimoxazole prophylaxis Monthly visits for ART collection for the first 6 months, then every 3 months thereafter
Infant ARV	Daily nevirapine from birth to 6 weeks
Viral load testing	Dried blood spot (DBS) HIV RNA testing at 6 months post ART initiation, 2 years, and every 2 years thereafter or in the event of clinical suspicion of failure based on new stage 3 or 4 condition after greater than 12 months on ART.
Infant HIV testing	DNA-PCR of infant dried blood spots (DBS) at 6 weeks HIV antibody testing at 1 and 2 years of age.
All procedures follow Malawi Ministry of Health integrated PMTCT/ART and HTC guidelines 2014. * This service will be replaced with the video-intervention for women randomized to the intervention group.	

Exclusion Criteria: Women already on ART; significant pre-existing psychiatric comorbidity at enrollment that may impact ability to provide consent according to the clinical judgment of study personnel (including cognitive impairment or known psychotic disorder); women who participated in the study pilot.

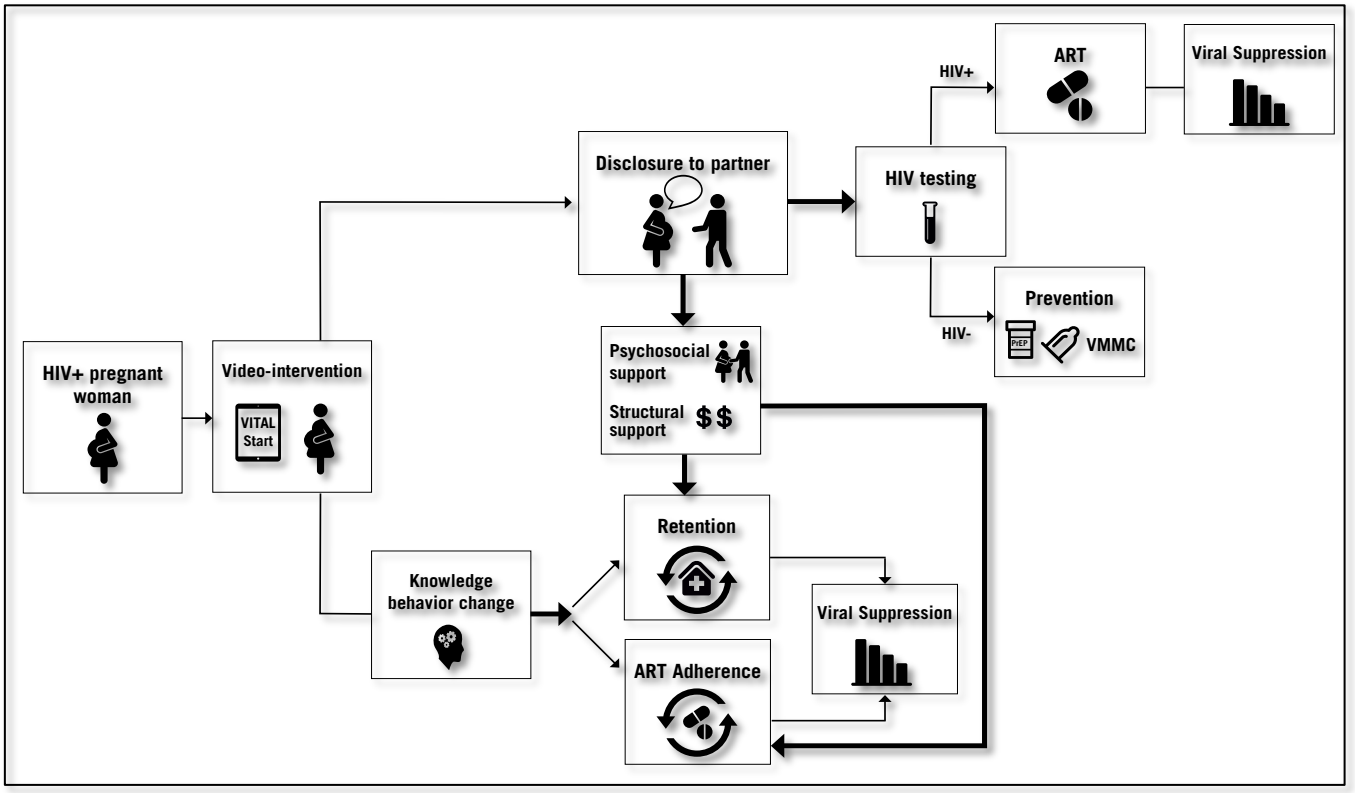
Recruitment procedures, consent, randomization, allocation procedures, and follow-up
Staff at the recruitment sites will use a standardized script to determine eligibility and interest in study participation. Eligible women who refuse to participate will be asked for reasons for refusal and this will be documented in the screening and enrolment log. Research staff will obtain informed consent. The study participants will be counseled about the nature of the study, required follow-up, and that the selection in the study group is random. Upon consent, participants will provide locator information (phone numbers, physical addresses, and directions) and complete a research staff administered questionnaire. Post intervention/control a shorter series of questions will be asked to assess changes in knowledge. The baseline questionnaire will include the following: socio-demographics, HTC history,

sexual behavior,[36] a brief knowledge, motivations and behaviors assessment,[57] experience of intimate partner violence (IPV) and other traumas,[36] partner HTC/sexual history,[36] adherence self-efficacy, perceived social support,[58] perception of received health services support, alcohol and drug use, anxiety and depression screening [59,60] If evidence of suicidality is present the research assistant will refer the woman to a psychosocial counselor.

Randomization and allocation concealment: Upon completion of the baseline survey women will be randomly assigned (1:1) to either the VITAL start group or current standard of care (SOC) only (control). We will perform the randomization stratified by clinic proportional to the number of potential eligible participants to be enrolled in the study at each clinic. Smith's randomization algorithm will be applied for random assignment of subjects to one of the two groups to reduce the degree of imbalance throughout the randomization process. A statistician will generate serial random randomization codes, which are labeled A or B, for each clinic. The code will be put in a sealed opaque envelope labeled with an ordered number. The research staff will maintain all sealed envelopes and open them one at a time to inform participants of their assignment after consent and enrollment. If the participant refuses to participate in the study after randomization, the next participant will not replace that participant but will be randomized again. The research staff, MOH clinic staff, and participants will be aware of the randomization. Separate study staff (blinded outcome assessors) will conduct outcome assessments including follow-up surveys. They will be blinded and therefore not informed of the participants' group assignment. However, persons blinded to treatment allocation will perform the randomization. Only after data collection is complete will one researcher will break the randomization code to input the group allocation within the pre-existing data set and enable between-group analyses. The statistician and lead researcher (MK) will remain blinded. All study participants will receive SOC B+ services (Table 2) available at the MOH clinics from HIV testing through maternal ART, follow-up, and infant testing. The only difference will be the type of pre-ARV counseling.

Intervention Group: Patients in the experimental group will receive VITAL start pre-ARV counseling (approximately 27 minutes video followed by 10 minute guided Q & A to reinforce key messages and provide an opening for individual counseling=approximately total 37 minutes). This will be delivered by study staff. We hypothesize (Figure 3) that VITAL start will improve partner disclosure with downstream effects of improved HIV testing, use of preventative services for those testing HIV-negative, and linkage to ART for those testing HIV-positive. We also hypothesize that VITAL start will promote knowledge acquisition and behavior change leading to improved maternal retention in care and adherence to ART (Figure 3). Research staff will receive a brief (approximately ½ day) training on implementing VITAL start. The training will include information on the importance of adherence to the participant's assigned treatment group.

Figure 3: Hypothesized pathway via which VITAL start may improve partner outcomes and maternal retention and adherence



Control Group: Patients randomized to the control arm will receive the usual standard of care (SOC) pre ARV initiation education with the National ARV Educational Flipchart (typically takes one hour).

Study Duration: We estimate enrolling all subjects within 3 years and will follow subjects until the last woman has reached 12 month follow up

Follow up: Participants will be asked to attend a study follow-up visit at 1 month, 3 months, 6 months and 12 months after enrollment, at a separate location and time from where they receive their ART refills to reduce confounding. Surveys may be done via phone if that is the participant's preference. At these visits, women will be asked to complete an outcome assessor-administered survey with validated tools to a brief knowledge, motivations and behaviors assessment,[57] experience of intimate partner violence (IPV),[36] partner HTC/sexual history,[36] adherence self-efficacy, perceived social support,[58] perception of received health services support, alcohol and drug use, anxiety and depression screening [59,60] and ART side effects. Dried blood spots for viral load (VL) testing will be collected at 6- and 12 months. We will collect an additional dry blood spot (DBS) at the 12-month visit. There will be shipped to the University of North Carolina Clinical Pharmacology and Analytical Chemistry Laboratory at Chapel Hill, North Carolina, USA for pharmacokinetic analysis. If participants fail to attend follow-up visits, tracing will be attempted by study staff. Consistent with other studies in Malawi, a transport allowance will be provided for each study visit.

Sample Size Calculation:
The primary outcome for this study is a composite outcome of retention in care and maternal viral suppression that has been used in similar previous studies.[32,119] This outcome was selected to measure the ultimate goal of ART use within PMTCT services: to keep HIV+ mothers engaged in care and virally suppressed to maximize the benefits of ART for both treatment and prevention. This outcome assumes that those not retained are not virally suppressed. The sample size calculation is

based on a comparison of the proportions of those in the intervention versus SOC arms reaching the combined primary endpoint at 12 months after maternal ART initiation. Pearson Chi-square test for Proportion Difference was used for calculation. A combination of various scenarios was considered for retention in care (50-90%), maternal viral suppression (50-90%) among those retained, and contamination rate (0-15%). A difference of 15% was selected as the smallest difference that would be of clinical significance. It is also assumed that an effect of this magnitude could be anticipated in this field of research.[217,218]

For the primary analysis in all subjects, accounting for up to a 15% contamination rate (pilot data suggests 0% contamination) and assuming 1:1 allocation ratio, and 5% attrition (based on transfer out rates from Ministry of Health data at study clinics in 2016[39]) to achieve 90% power to detect a minimum difference of 15% between the control and intervention group, 796 subjects are required (398/398 per arm) at a significance level=0.025 to account for multiple comparisons. Given the anticipated policy change to a dolutegravir-based regimen in the near future, we have further increased the sample size by 12%, to 446 per arm. This increase was done due to published evidence demonstrating higher rates of viral suppression and lower rates of discontinuation in patients on dolutegravir-based regimens. We increased the sample size because this would make a difference between our study and control groups more difficult to measure. We will also plan to have a small pilot of new trial tools and procedures. We estimate that approximately n= 30 to 50, will be needed for adequate piloting. However, given much less contamination than anticipated and disruptions caused by the COVID-19 pandemic which culminated in complete suspension of enrollment from April through July 2020, the study enrolled 800 participants in total.

Outcome Measures

The main study outcomes are (1) composite of retention and adherence (viral suppression); (1b) behavioral adherence; and (1c) knowledge and psychosocial impact. Additional outcomes and schedule of measures are outlined in Table 3. Retention will be defined as alive and receiving ART, as per clinic verified records, within 3 months of the 12-month endpoint. Viral suppression will be defined as <1000 copies/ml. We will also collect data on factors that might impact the primary outcome (as described above).

Infant outcomes: We will also abstract data and/or ask the mother information regarding pregnancy and infant outcomes from existing MOH patient records. Data will include information related to the pregnancy and delivery (ie. pregnancy loss, stillbirth, date of birth, gestational age at birth, pre-term birth, small for gestational age, congenital anomalies, birth weight), and data related to the infant, (ie. infant HIV test dates and results, infant ART initiation date, infant retention and survival outcomes, and outcome dates).

Table 3. VITAL Start study outcomes and schedule measures

Schedule (Month number)
Informed consent
Aim 1 Retention and Adherence (VL<1000 copies/ml) at 12-month
Retention in care (Data abstraction from electronic medical records)
Viral suppression (VL <1000 copies/ml)123,165 DBS collection for VL at 6 and 12 months
Aim 1b: Behavioral adherence
Self-reported adherence
Pharmacy refill data abstraction
DBS for pharmacokinetic analysis at 12 months

Aim 1c: Knowledge and psychosocial impact
HIV/ART knowledge and attitudes survey
Adherence self-efficacy
Motivation & behavior skills assessment-Life Windows Tool
Self-reported partner disclosure171 and World Health *Organization intimate partner violence survey and other traumas*
Multi-dimensional scale perceived social support (MSPSS)
Self-perceived quality of care
Aim 2: Implementation outcomes
Participant satisfaction surveys
Interviews with participants, partners, health care workers
Study fidelity evaluations
Contamination assessment
Time-motion assessments in line with STAMP checklist
Aim 3: Cost-effectiveness analysis. Data collected throughout study period

Table 4 outlines the potential moderators of primary health outcomes that may be measured at baseline and follow-up visits.

Table 4. Potential moderators of primary health outcomes
Collected at Baseline
Maternal socio-demographics: age, educational level, literacy, hunger in past month, mom employment status, economic status, self-reported comfort with technology and literacy, pregnancy information [trimester of pregnancy, primiparous, number of children],
Maternal sexual history: duration with current sexual partner, number of sex partners in past year[36]
HTC history: never tested, previously negative, previously positive, previous history of couples HIV testing and counseling
Partner related: partner age, education status, employment status, perception of partner HTC history[36] (no test/does not know, negative, positive, indeterminate), perception of partners sexual activity (number of sex partners in past year, belief partner has had other partners in the past year),[36] experience with intimate partner violence (IPV) or perceived threat of IPV (yelled at or threatened by partner, physically hurt by partner, fear of partner being angry with disclosure, fear of being left by partner if disclosed, fear of being hurt, fear of partner telling others)[36]
Maternal health behaviors and depression: adherence self-efficacy, family planning related, alcohol/drug use, perceived social support [58] depression and anxiety[60] ART side effects

Data collection and management

All questionnaires used for data collection purposes will be translated into Chichewa (the local language), back-translated, and pilot tested prior to use, and will be administered by study staff. Attached here is the draft questionnaire.

Data analysis plan:

The intent to treat (ITT) population is defined as all randomized subjects, regardless of when they withdrew from the study. We will exclude the ineligible patients and thus perform modified ITT analysis as the primary analysis to facilitate interpretation if the exclusions do not disrupt the baseline equivalence established by random assignment and bias the results. We also include who completed the intervention, and with follow up data to conduct secondary and exploratory analyses of the secondary efficacy data and explorative outcomes, for example viral load, which is only available at month 6 and 12. There is no planned interim analysis for this study. All hypothesis testing will be

carried out at the 5% (2-sided) significance level unless otherwise specified. Additional ad-hoc analyses may be conducted as deemed appropriate and any changes, including the rationale for use will be documented in the clinical study report. All statistical analysis will be performed using SAS® v9.4, R 4.2.2, Stata 17 or higher for Windows.

Demography and baseline characteristics include age, socioeconomic, pregnancy and HIV variables. etc Descriptive statistics, such as, mean, standard deviation (SD) for continuous variables, and frequency and proportion for categorical variables, will be calculated by treatment group. Baseline differences will be compared using two-tailed independent t-tests (means) and chi-square tests (%) to evaluate the balance of patient characteristics in two groups by the randomization.

The primary efficacy endpoint is the composite outcome of achievement of retention and viral suppression at Month 12. The primary efficacy endpoint will be analyzed using a binary goal attainment variable (is the achievement of retention and viral suppression [1 yes/0 no]). Participants will be considered retained in care if they are verified by clinic records as active on ART. Retention (1 Yes) will be defined as alive and attending ART clinic, as per clinic verified records, within specified window of the follow up visits. All else without known status or retention information (Due to stopped, LTFU/defaulted, transferred out, missed appointment, and missing) will be defined as Retention (0 No). Amongst those retained the study will then assess viral suppression which will be measured as viral load less than 1,000 copies per milliliter. A sensitivity analysis using detectable vs. undetectable viral load will be performed. Missing viral load information will be treated as not suppressed. There is no missing data on the primary outcome by definition.

The number and proportion of subjects who achieved retention and viral suppression at Month 12 will be summarized by treatment group. The comparison of the proportion of success in the two treatment groups will be conducted using Chi-square tests followed by logistic regression including treatment, center, and other baseline prognostic factors. Important baseline prognostic factors of the main outcome (p-values < 0.2 from univariate analysis) will be entered into the model. The main exposure variable and any factors, such as age, prior history of ART, deemed to be clinically relevant will be forced into the model regardless of the statistical significance. A backwards selection procedure will be performed to select other factors. Variables achieving statistical significance will be retained in the model. Covariates will be checked for collinearity using the variance inflation factor. Where collinearity occurs between two variables, only one of these variables will be included in the final model. An assessment of the model goodness-of-fit will be performed using the Hosmer-Lemeshow test, deviance test, and visual inspection of index plots. The adjusted odds ratio of achieving retention and adherence at Month 12 on VITAL Start versus Control will be reported along with the 95% confidence interval and 2-sided p-value.

Secondary efficacy outcomes include achievement of retention and viral load suppression at month 6, retention at month 12, viral suppression at month 12, TFV-DP and 3TC adherence status at month 12 (for selected subcohort), and self-reported adherence status at month 12. The statistical method detailed above will be applied.

Other explorative measures include knowledge inventory, patient-Provider relationship, pregnancy intention, satisfaction with the counselling, adherence-self efficacy, partner disclosure, motivation and behavior skills, perceived social support, self-Reporting Questionnaire (SRQ)- Mental health assessment (depression and anxiety), adverse Childhood Events – International Questionnaire (ACE-IQ), cigarette use, alcohol use disorders identification test (AUDIT), drug use disorders Identification Test (DUDIT), family planning intentions, side effects, intimate partner violence (IPV), contamination measures, infant outcomes and COVID-19 impact. Descriptive statistics will be calculated for all measures and displayed by treatment group and visit as appropriate. For continuous outcomes, such as ART knowledge measures, adherence self-efficacy score, motivation and behavioral skills, perceived social support score and self-perceived patient-provider quality of HIV care score, two-

sample t-tests will be used to compare 12-month outcomes and linear mixed models will be used to examine differences in trajectories over time between the intervention and control groups. For categorical outcomes, the number and proportion of the categories at Month 12 will be compared using Chi-square tests. Generalized Estimating Equation (GEE) method for repeatedly measured categorical outcomes will be applied to compare the outcome across time between two groups while accounting for the correlation among repeated measures from the same subject.

Specific aim 2: To critically examine the delivery of VITAL start via in-depth interviews and surveys administered to patients, partners, and health workers. Adoption and satisfaction with the program will be measured. Qualitative interviews will be utilized to obtain feedback on motivational qualities of the program and benefits and challenges of delivery.

Participant eligibility and recruitment: All participants enrolled in the study, their partners, as well as healthcare providers working at the study sites will be eligible for participation. Purposeful sampling will be used to maximize variability in the sample, ensuring that a broad range of views, demographic factors (for example, income age, marital status), social factors, study sites, and outcomes (disclosed to partners/LTFU) are represented.

To assess overall satisfaction with the intervention both HCWs and study participants will be asked to complete satisfaction surveys. In addition, an objective assessment regarding the impact of the intervention on HCW efficiency and time spent on counseling will be conducted with use of time-motion assessments in line with the STAMP checklist (Suggested Time and Motion Procedures).[62,63]

Interviews: To further explore implementation issues that may be unique for women, partners, and HCWs, we will conduct in-depth interviews. We plan to interview approximately up to ~100 women (50 intervention/50 control group), 40 partners (20 intervention/20 control group), and 40 HCWs with the final sample size determined by data saturation. Women will be invited by the research assistant to participate in qualitative interviews during follow up visits. Some women may be asked for repeated interviews (for example at baseline, 1 month follow up as well as 6 month follow up). A sample of partners of women participating in the study will be recruited for participation. Study staff will invite healthcare workers.

Data collection: *Interview guide:* The study team and interviewer(s) will co-develop the guides. All participants will be asked about their views on the feasibility and acceptability of the video intervention, as well as its strengths, suggestions for improvement, motivational aspects, and the challenges and benefits they experienced. We will assess if the video accurately communicated intended educational messages, and if unintentional messages were portrayed. We will ask about experiences with partner disclosure and ART adherence. We will also use qualitative research to help explain/describe quantitative findings. HCWs will be asked about the challenges and benefits to implementing VITAL start and its potential impact on the health facility and patients. They will also be asked about the integration of videos into others aspects of health care delivery. To ensure proper translation, the patient guide will be translated into Chichewa, back-translated into English, pre-tested and revised to ensure comprehension. *Interviewers:* experienced qualitative interviewers will conduct the interviews. *Interview procedure for all participants:* Interviews will be conducted at the location of the participants choosing or via phone if that is the participant's preference. Informed consent will be obtained for enrollment in this nested sub-study from all participants. Interviews will be conducted in Chichewa, unless the participant is fluent and wishes the interview to be conducted in English. Interviews are expected to take 30 to 60 minutes and will be digitally recorded and transcribed verbatim. Interviewers will also take notes during the interviews.

Data analysis: *Transcription:* Recorded interviews will be transcribed verbatim and translated into English and occur concurrently with data collection. *Coding:* Transcript text will be read and re-read carefully to: (1) become familiar with each individual situation; (2) identify text that may be unclear due

to differences in the cultural context; (3) point out areas in which interviewing techniques could be improved; and (4) identify recurrent themes. We will use standard qualitative content analysis approaches for thematic analysis of the transcripts. Study staff experienced in qualitative data analysis will code the scripts and establish a coding scheme. The developed coding scheme will be refined to enable one research team member to independently code the remaining transcripts, with revisions made as necessary to reflect new and evolving themes. Thematic analysis will occur concurrently with data collection to allow further exploration and clarification of emergent ideas, and data collection will continue until data saturation is reached. Transcribed interviews and digital files will be stored on a password-protected computer, and when not it use will be stored under lock and key. All data will be anonymized for publication. Only researchers affiliated with the study will have access to participant data.

Specific aim 3: To assess the cost-effectiveness of the VITAL start intervention. Cost-effectiveness will be assessed using incremental cost-effectiveness ratios, with health effects expressed in term of viral load suppression and costs of resources used for the intervention.

Costing: The MOH will be the main implementer of the VITAL start intervention as well as standard of care pre-ART counseling. Therefore, we will assess costs from the provider (MOH) perspective. We will use both micro and macro based approaches as appropriate to identify and quantify intervention resources. [64] Retrospectively, we will extract information on resources expended for video design and production from inventory and other BCM-CFM Tingathe program documents. Unit prices will be obtained from accounts records or from local retailers.

Prospectively, we will collect information regarding costs of administering both the VITAL start and the SOC pre-ART counseling. To measure staff time devoted to pre- ART counseling, we will perform time-motion assessments in line with the STAMP (Suggested Time and Motion Procedures).[62] We will sample sufficiently to account for potential sources of heterogeneity such as study clinic and provider. We will randomly sample provider sessions from each arm of the study and each participating study clinic during every month of participant enrolment. A minimum of 4 assessments will be conducted per clinic every month. Therefore, we anticipate collecting data on over 200 pre-ART counseling sessions. Repeat sampling of providers is expected and will be recorded. The value of staff time will then be estimated as the product of their gross salary and share of time allocated to intervention/pre ART counseling.

Cost effectiveness analysis: We will calculate incremental cost-effectiveness ratio (ICER), for the primary outcome of economic interest: proportion of women virally suppressed at 6 months follow up. The ICER is the difference in costs between two interventions divided by the difference in their effects, and can be interpreted as the incremental price of a unit health effect from the intervention under study, as compared to the alternative.

We will conduct one way and multi-way sensitivity analysis to model cost-effectiveness under various conditions, such as lower pricing of video production, mode of delivery, tablets, and alternate health care workers cadres to deliver the intervention. Finally, we will conduct probabilistic sensitivity analysis using bootstrapping methods to ascertain robustness of our results to extreme assumptions/scenarios. Based on emerging literature,[65] we will define VITAL start as cost-effective if its ICER is< 50% of Malawi GDP (0.5x$250=$125/YLS), compared to standard pre-ART counseling. We will also consider alternative thresholds of 100% and 300% of GDP.

RISKS/BENEFITS TO SUBJECTS AND DEALING WITH ADVERSE EVENTS

The risks to participating in this study are minimal and are primarily related to issues of confidentiality. Potential breach of confidentiality may occur, although multiple safeguards, as outlined below will be put into place to minimize this risk. Study participants may feel psychological distress during participant interviews. Although this has not been documented in other studies seeking to improve partner involvement, because the intervention does seek to promote partner involvement there may be

a risk of intimate partner violence. Participants may feel coercion to participate in the activities. By using an informed consent, all participants will be given sufficient information to make an educated decision about participation.

We are taking precautions to limit any emotional harm to participants that the interview process may cause patient participants. Consents will remind participants that they may decline to respond to any item(s) during study interviews, and may end study participation at any time without affecting the quality of health care they receive or current state of employment (HCW). We will ensure that mechanisms are in place in case participants experience intimate partner violence, distress or express suicidality on depression screens. Mechanisms will include counseling by study personnel, and referral to a psychosocial counselor trained in managing domestic violence and psychological issues.

Disclosure of medical or other personal information about participants, particularly HIV status and social issues such as intimate partner violence, may result in negative stigma being associated with the individual and/or family. We will take all possible precautions against breaches of confidentiality to minimize this risk (as explained in detail below).

Potential benefits of the proposed research to human subjects and others
Women in the intervention group may benefit from receiving the VITAL start intervention, which is designed to enhance partner engagement as well as self-management skills related to medication adherence. This in turn may decrease risk of mother-to-child HIV transmission, while maximizing maternal health. We believe the potential benefits outweigh the risks. Women in the control group may also benefit from participation in the baseline and follow-up surveys, which may encourage conversation between the women and her partner. All participants may receive a psychological benefit by talking to someone about their health care experiences. Likewise, health care providers, and key informants may receive psychological benefit by talking to someone about the challenges they have experienced while trying to provide PMTCT care. All participants may receive additional psychological benefit knowing that their participation may contribute to the understanding of new insights on barriers to care for PMTCT recipients. By contributing to the evidence base outlining high-yield and scalable approaches to improving PMTCT retention and partner involvement, this study offers a potential indirect benefit to other HIV-positive pregnant women.

HIV-positive pregnant women face barriers to involving their partners in PMTCT and remaining adherent to ART. Few theory-based behavioral interventions have been rigorously evaluated, and none that utilize videos. This is the first trial to examine the effects of a video-based intervention for partner engagement as well as HIV prevention and care amongst PLHIV in sub-Saharan Africa. By evaluating the efficacy of a brief facility-based video intervention, the research team will expand knowledge regarding effective ways to educate and promote behavior change amongst HIV+ pregnant women. Moreover, data gained from this study will help establish the feasibility and potential impact of video-based interventions as a means for health education and behavior change in resource-limited settings. With the global move towards universal ART treatment, and rising burden on health care providers, the need for evidence-based, inexpensive, scalable interventions that provide high quality pre-ART education and promote life-long adherence to treatment will be critical. This study will provide evidence regarding a potentially highly effective, cost-effective model: brief video-based interventions. This research will inform research on technology-based partner engagement and maternal adherence promotion interventions and will have broader implications on video-based interventions across health domains in sub-Saharan Africa.

COSTS AND COMPENSATION:
There are no costs to the participant for taking part in this research. However, transportation costs will be reimbursed at $5 USD. In addition, they will also receive a small snack during the interview.

CONFIDENTIALITY ASSURANCES/ETHICAL CONSIDERATIONS

All study participants will undergo informed consent by trained study staff, using IRB-approved informed consent forms in either Chichewa or English depend on participant preference. The consent form and study materials will be approved by the Institutional Review Board of the National Health Sciences Research Committee in Lilongwe, Malawi and by the Baylor College of Medicine Institutional Review Board.

We will take all possible precautions against breaches of confidentiality. All research personal will be trained in the need for absolute confidentiality. We acknowledge that a breach of confidentiality is possible, however we anticipate that the likelihood is very low given the precautions taken to protect confidentiality. Our efforts will include:

1. All staff will be trained in confidentiality and data security procedures using open-access standardized online modules provided by the Collaborative Institutional Training Initiative (CITI), a recognized leader in research training that is not affiliated with the study.
2. Privacy will be maintained by conducting all study procedures in private areas. Data will be rendered anonymous to the degree possible to minimize likelihood of any individual being identified. Only study identification numbers will be used for data abstraction and analysis. The only forms containing patient names will be informed consent forms, and these will be secured in a locked cabinet only accessible to key personnel.
3. All electronic data will be password protected and stored in a password protected and encrypted computer secured in a locked cabinet when not in use. Only select devices maintained with password protections and encryption will be allowed access to study data.
4. Data transfer will only occur over encrypted networks.
5. All analysis will be conducted only on de-identified data.

INFORMED CONSENT

Informed consent will be obtained from all patients, partners, and health care providers. Consent forms with information regarding the study have been translated from English to Chichewa and then back-translated into English by a co-investigator fluent in Chichewa who has experience translating study consents in Malawi. Consent will be obtained via the following procedure:

1) Health care providers will be given the written consent form to read. For patients or other participants who are unable to, or are uncomfortable with reading the consent study staff will read the form aloud to the patient. Study staff will periodically stop reading and will ask the patient if she has any questions. All participants will be encouraged to ask questions if they do not understand the information.
2) After the participant finishes reading the form, or the form has been read (patients), study staff will briefly summarize the information in the consent form and ask the participant if she/he has any questions. If the participant did not understand the information, the study staff will repeat and explain the specific information that was not understood.
3) After all questions have been answered to the satisfaction of the participant, the provider/key informant will be asked for their written agreement. For patients, if the participant is unable to sign their name, the study staff will obtain a thumbprint. The study staff will also sign, print, and date the form to acknowledge that the individual gave their verbal agreement. For patients who are illiterate, study staff will ensure that a witness is present during the consent process and the witness will also sign, print and date the form to acknowledge that the individual gave their verbal agreement.
4) Copies of both the English and Chichewa forms will be provided to those participants who wish to take a copy.

5) Consent forms will be kept for three years after the completion of the investigation and will be maintained according to GCP guidelines at a central location. The key will only be available to the PI and study staff.

CONFLICT OF INTEREST

The PI and co-investigators state that we do not have any real or apparent conflict of interest. We have no additional gain, other than scholarly gains, by participating in this study.

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Consent for general study participation

Why is this study being done?

This study is being done by researchers from the Baylor College of Medicine Abbott Fund Children's Clinical Centre of Excellence-Malawi (COE). We have made a video program for pregnant mothers to help you learn about being HIV-positive, taking medications, and keeping you and your baby healthy. We would like to learn about using this video in the clinic and whether the video helps women and their family members stay healthy. We will use the information learned from this study to try to help make HIV services in Malawi better.

I am a member of the study team and I am going to give you information and invite you to be part of this research. If this consent contains words or ideas that you do not understand, please ask me to stop and explain. If you have questions later, please also feel free to ask me or another member of the study team at any point.

What happens if I join this study?

If you choose to take part in this study you will be randomized to either the video counseling or to continue with the standard pre-ART counseling and services available at the health facility. Randomized means that you might be assigned to receive standard counseling, or you might be assigned to the video counseling.

If you are assigned to receive only the standard pre-ART counseling you will not receive the video counseling. If you are assigned to the video counseling, you will continue to receive all the usual services available at the health facility—the only addition will be the video counseling.

You will also be asked to answer questions asked by the study team member regarding you, your family, and your knowledge and use of HIV and prevention of mother-to-child transmission of HIV (PMTCT) services. Questions will include topics such as your experiences with HIV testing and/or treatment, your pregnancy, past pregnancy history, information about your relationship with your partner including any experience with partner violence and other past traumas, questions about your feelings on your ability to take ART, social support, alcohol and drug use, as well as an assessment for depression.

You will also be asked to participate in follow-up assessments approximately 1, 3, 6, and 12 months after enrollment. During these follow-up visits a study staff member will ask you questions. Questions will include topics such as about your partner, how often you are taking your medicines, whether you are having side effects. We will also ask about the support you receive at home, your experiences with health services, infant birth and medical information, family planning intentions and about your mood. You will be asked to provide a small amount of blood (less than a teaspoon, dried blood spot) at 6 and 12 months after you begin the study. This blood will be collected by a small finger prick and will be used to see how much HIV is in your blood. Your blood may also be checked to measure the amount of medication in your body and whether or not the medicines are working. Your sample would be shipped to the University of North Carolina laboratory in Chapel Hill, USA for these tests. These follow-up study visits are separate from the usual ART medication refill visits. The follow up surveys will take place at a different location and time from where and when you receive ART refills. If you do not attend follow-up visits, study staff members may try to contact you.

We will also gather information from your medical record about HIV testing and treatment for you and your infant. For example, information regarding your clinic visits, pregnancy information, your child's birth history, and HIV testing and medical treatment.

Is my participation voluntary?

Taking part in this study is voluntary. This means that you may refuse to join, or you may withdraw your consent to be in the study at any time for any reason. We ask that you inform study staff of the reason if you make that decision. Your decision will not change any present or future access to services through the organizations involved in this study or access to services at the health facility. The investigators also have the right to stop your participation at any time.

Who will see my information?
If you agree to take part, all information collected during the study will be kept confidential. Your name will not be written on the study forms and will not be used in connection with any information or laboratory specimens that are collected as part of the study. All study materials will be stored in locked filing cabinets. Only study staff and personnel involved in routine audits will have access to these materials. All staff involved in data collection and management are trained in keeping your information confidential. Your name will not be used during audio recordings.

Some of your health information and results of study tests will be kept by us in a central research database. However, your name and contact information will not be put in the database. This data (without your name and contact information) may be shared with other organizations who will help study the data.

There are organizations that may look at your study records. They must keep your information private, unless required by law to give it to another group. Some of these organizations are the study sponsor and the IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.

How long will I be in the study?
You will be in the study for approximately 12 months

What are the possible discomforts or risks?
While we do not anticipate the study will cause you distress or any social harms, a psychosocial counsellor will be available. Further, at any point you may choose to not answer any questions, or to end the interview. Drawing blood by a finger prick can cause mild discomfort.

What are the possible benefits of the study?
You may find it helpful to talk about your experiences with someone. Research is designed to improve society by generating new knowledge. The information you tell us may help children and families in Malawi by improving PMTCT services in Malawi.

Will I be paid for being in the study?
There are no costs to you for taking part in this research. You will receive a small amount of money to help with transportation to follow-up visits equivalent to $5.

What are my rights as a research subject?
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study. You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

Who do I call if I have questions?
If you have questions or concerns at any time, you may speak with a member of the study staff Mr. Alick Mazenga at 01750 877. You may also contact Dr. Ben Chilima, chairman of the National Health Sciences Research Committee (NHSRC) at 01 726 422 or 01 726 418.

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

A description of the study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. The Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

Title of Study: VITAL start: VITAL Start (Video-intervention to Inspire Treatment Adherence for Life): Brief facility-based video intervention to improve retention and adherence to ART among pregnant and breastfeeding women

Verification of Consent:

I have read the information about this study, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Print Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/Month/Year

If illiterate
I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness: _____Thumb print of participant

Signature of witness: _____

Date: _____
Day/Month/Year

Statement by the researcher/person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the purpose and protocols of the study. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Print Name of Study Staff taking the consent: _____

Signature of Study Staff taking the consent: _____

Date: _____
Day/Month/Year