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“COMPUTER-BASED COUNSELING PROGRAM (CARE+ KENYA) TO PROMOTE PREVENTION AND HIV HEALTH FOR PEOPLE LIVING WITH HIV/AIDS: A RANDOMIZED CONTROLLED TRIAL”

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Abstract

In countries experiencing the dual burden of human immunodeficiency virus (HIV) disease and health care worker shortages, information and communication technology tools offer a potential solution to help support HIV treatment adherence and secondary HIV transmission risk reduction for people living with HIV/AIDS. We conducted a randomized controlled trial (September 1, 2011 – July 12, 2012) with follow-up through April 2013. Participants were recruited from two clinics affiliated with the Academic Model Providing Access to Healthcare program in western Kenya. A total of 236 participants were enrolled, randomly assigned to intervention (n=118) or risk-assessment only control (n=118) and followed up for 9 months; with 95.3% retention. Both arms had > 0.5 log₁₀ reduction in viral load over time (p=0.0007), a clinically relevant finding. A computer-based counseling tool is feasible and acceptable to implement in a high-volume East African HIV setting and provides evidence-based ART adherence and risk reduction support that may extend health workforce deficits.

Trial Registration: [ClinicalTrials.gov](https://clinicaltrials.gov)

Keywords

Computer-based counseling; HIV; Viral load; ART adherence

Introduction

The Joint United Nations Programme on HIV/AIDS (UNAIDS) announced, and the United Nations has now endorsed important goals by 2030, 95% of people living with HIV/AIDS (PLH) should know they are positive, of those who know they are positive 95% should be in treatment, and of those in treatment, 95% should be virally suppressed (Joint United Nations Programme on HIV/AIDS [UNAIDS], 2014). Current progress towards the 95-95-95 HIV treatment cascade demonstrates improvement, with three quarters of PLH who know their HIV-positive status, 79% of those with known positive status on antiretroviral treatment (ART), and 81% of those on ART achieving viral suppression worldwide (UNAIDS, 2018). However, despite advances in treatment and outcomes, the number of people living with HIV continues to grow, estimated at 36.9 million with 21.7 million on ART (UNAIDS, 2018). The United Nations deems eastern and southern Africa as the “world’s most affected region” by HIV/AIDS (UNAIDS, 2016). Overall AIDS related deaths continue to decline, but only eight countries, including Kenya, bear 53% of global AIDS-related deaths (Granich et al., 2015; UNAIDS, 2016).

The still pressing need for expanded and improved HIV care in sub-Saharan Africa is further complicated by healthcare worker shortages, requiring varied and multi-sectoral solutions (Kinfu, Dal Poz, Mercer, & Evans, 2009; Van Damme, Kober, & Kegels, 2008). For example, task-sharing, where each cadre contributes at the top of education and skillset, improves patient outcomes, provides similar or better quality of care, and increases access to care where healthcare shortages exist (Callaghan, Ford, & Schneider, 2010; Sanne et al., 2010). Further innovation and multi-disciplinary approaches are necessary for greater HIV treatment and prevention (Camlin et al., 2016). Use of technology may be another avenue to ensure medication adherence and promote secondary HIV transmission risk reduction in the HIV continuum, targeting behaviors that prevent the transmission of HIV by PLH and effecting behavior change (Auerbach, 2004; Kennedy, Medley, Sweat, & O’Reilly, 2010).

A study conducted in western Kenya reveals the repercussions of the health worker shortage and large HIV infected population – little time spent with patients and lost opportunities for counseling with very little counseling on secondary HIV transmission risk reduction and the majority of clinic visit time (66%–78%) spent waiting (Were et al., 2015). This finding is not unique, as a similar study conducted in two Ugandan HIV clinics demonstrates comparative wait times of 62%–66%, presenting opportune moments for further patient care and counseling (Were et al., 2008).

The Computer Assessment & Rx Education for HIV-positive people (CARE+) (Skeels, Kurth, Clausen, Severynen, & Garcia-Smith, 2006), provides personalized virtual counseling via an evidence-based computer software program and has been associated with improved ART adherence, reduced HIV transmission risk behaviors, and decreased viral loads (VL) in U.S. English and Spanish speaking populations, although not statistically significant in the later (Kurth et al., 2014; Kurth et al., 2016). With overall user acceptability, supportive healthcare provider feedback and designation of the Centers for Disease Control and Prevention (CDC) “best evidence” for risk reduction (Centers for Disease Control and Prevention [CDC], 2014), the tool may be useful in resource-limited settings. The targets of

the CARE+ intervention – increasing medication (‘Rx’) adherence, suppressing viral load, and reducing risky sexual behaviors associated with transmission – are key to reducing morbidity/mortality and transmission of HIV disease (Gill, Hamer, Simon, Thea, & Sabin, 2005; Person, Ramadhani, & Thielman, 2007; Simoni, Pearson, Pantalone, Marks, & Crepaz, 2006). In general, counseling and motivational interviewing are effective means to promote risk reduction, and an intervention that does not necessarily rely on the already strained human resources for health, could prove a break-through in reaching the 95-95-95 targets (Kanekar, 2011; Lambdin et al., 2015).

We hypothesized that a computer-delivered counseling intervention, adapted for use in a diverse cultural and linguistic setting in a high-HIV burden, low-income country setting, can help address health workforce deficits, and support ART adherence and secondary HIV transmission risk among PLH. We evaluated the efficacy of this intervention (CARE+ Kenya; Figure 1), at two clinical sites (Burnt Forest [BF] and Moi Teaching Hospital Module 1 [M1]) affiliated with the largest HIV care provider in Kenya, the Academic Model Providing Access to Healthcare (AMPATH) (Einterz et al., 2007).

Methods

Participants

Randomized Controlled Trial—In order to assess the efficacy of a computer-based counseling program (CARE+ Kenya) on ART adherence and positive prevention specifically in a sub-Saharan African setting, a randomized controlled trial (RCT) was conducted from September 1, 2011 to July 12, 2012. RCT follow-up continued to 2013, and an implementation phase to 2014. Participants were recruited from two clinical sites, a rural (BF) and an urban clinic (M1) within the AMPATH program in western Kenya (Were et al., 2015). Eligibility criteria were (1) adults (age ≥ 18 years), (2) seen for care, including ART at the clinics, (3) able to understand spoken Kiswahili or English, and (4) reported sexual transmission risk or less than “perfect” ART adherence defined as any of the following: any missed dose or pill counts that indicate non-adherence with medication or delay in pharmacy refill, unprotected sex in the last 6 months or more than 1 sexual partner in the last year, or any sexually transmitted infection (STI) diagnosis in the last 3 years.

Written informed consent was obtained prior to randomized assignment. All study procedures were approved by Moi University College of Health Sciences and Moi Teaching and Referral Hospital’s Institutional Research and Ethics Committee (#IREC/2009/115), Indiana University Institutional Review Board (#0905–68) and NYU’s University Committee on Activities Involving Human Subjects (#10–0684). Participants received 300 KSh (~3.00 USD) for their time and to reimburse their transportation costs at the end of each study visit (4 sessions total). This level was determined by the Kenya IRB not to be coercive.

The RCT participants were enrolled by research assistants affiliated with AMPATH/Moi Teaching and Referral Hospital. A list of potential participants with scheduled clinic visits at BF and M1 were generated weekly from AMPATH’s Medical Record System (AMRS) and securely shared with research assistants. When potential participants presented themselves for their clinic visit, they were informed of potential study eligibility by clinic staff (i.e.,

desk clerk or nurse) and were directed to the research assistants. Research assistants also directly approached potential participants in the waiting room areas of the two study sites. Anyone interested in learning more about the study was taken to a private area, assessed for eligibility, and enrolled if they met inclusion criteria and provided informed consent. All research assistants completed training on human subjects' protection certification, and received training on the study protocol and procedures, and the use of the CARE+ Kenya program.

Intervention

The computer-based CARE+ Kenya counseling intervention, delivered using touchscreen tablets, was evaluated using a prospective randomized two-arm RCT design. The software, previously described (Kurth et al., 2016; Kurth et al., 2014; Skeels et al., 2006), randomizes the participant automatically to the control or intervention arms when the user first logs into the program, using a quasi-random sampling method. The quasi-random number algorithm for the sampling method was created from a list of randomly generated numbers, arranged in ascending order. The first assignment was determined at random, subsequent assignments were done at regular intervals in a systematic manner. This sampling method ensured even distribution of participants in both the control and intervention groups. Participants were guided through the counseling program using audio narration of all content in English or Kiswahili. The intervention group received audio-narrated assessment, tailored feedback, skills building videos, health plan, and print-out that could be shared with their health care provider. The intervention session lasted approximately 30 to 60 minutes. The control group received risk assessment only, which included questions about their behaviors such as sexual risks, alcohol and substance use, and other questions such as mental health, partner disclosure and status, social support and medication regimen adherence in the last 7 (missed dose) and 30 days (visual analog scale; VAS), along with side effects. The control session lasted approximately 15 minutes. Each group underwent four sessions total at 3-month intervals (at 0, 3, 6, and 9 months). Study sessions were scheduled to align with clinic visits when possible.

In both arms, the CARE+ Kenya program flagged reports of severe depression using the Patient Health Questionnaire (PHQ-9 score ≥ 20), potential suicidal ideation, and intimate partner violence (IPV) risk for appropriate referral and follow-up.

Focus Groups—Focus groups were conducted at the two sites (BF and M1) with a small subset of RCT participants who were assigned to the intervention group to gather feedback about the CARE+ Kenya counseling program. Participant focus groups took place from February 13, 2014 to September 18, 2014, with a total of eight sessions conducted (three for M1 and five for BF); the sessions lasted approximately 1.5 hours. The focus groups were conducted using a structured guide to explore the following topic areas: sources of health information, acceptability of the counseling tool, and challenges and facilitators to use of the tool. At the end of the session, participants were given transportation reimbursement in the amount of 200 KSh (~2.00 USD).

Outcome Measures

The primary outcomes were ART adherence and sexual transmission risk behaviors. ART adherence was measured by HIV-1 viral load, electronic monitoring (eCAPs), pharmacy refill, pill count, self-report, and clinic attendance. Blood samples were collected in both arms to measure HIV-1 viral load at baseline and the 9-month study visit. We assessed the differences in log10 viral load between the control and the intervention arms. Those with undetectable viral load were assigned a value of zero. However, for reasons of ensuring that the sample sizes remained the same we added a value of 1 to the viral load for all participants. This was meant to cushion against getting a missing value for log10 viral load when the logarithm of zero was computed. Electronic pill monitoring was used to track antiretroviral medication adherence; eCAP data were captured at each patient refill visit (monthly) and at their study session visit. HIV transmission risk was measured by self-reported unprotected sex with a partner who was HIV-negative or of unknown HIV status, and trends in sexually transmitted diseases: *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Urine specimens were collected at baseline and the 9-month visit to measure these trends.

Sample Size Determination

Sample size calculation was based on the target intervention effect on the primary outcomes: HIV viral load at log10 scale and occurrence of unprotected sex with an HIV-negative/unknown partner(s). All calculations control type I error rate at 0.05. Considering a 0.5 log10 HIV viral load decrease as a meaningful reduction, with 100 retained subjects in each arm, there was an expected 80% power to detect this difference with a standard deviation of 1.25 (effect size=0.4).

Statistical Analysis

Fisher exact, two-sample t-test, and Wilcoxon rank-sum tests assessed differences between intervention and control groups. Generalized estimating equations (GEE) and mixed effects linear models were used to evaluate the CARE+ Kenya program impact on primary outcomes, which included ART adherence, HIV-1 viral loads, and sexual transmission risk behaviors.

Focus Group Analysis

Data from the focus groups were transcribed and reviewed by SM. Data were analyzed and emergent themes were categorized with the goal of identifying acceptability and utilization of the computer counseling tool.

Real-world Implementation

After the RCT, we implemented real-world utility of the CARE+ Kenya program to assess whether the counseling tool can be integrated in a high-volume health setting to support safe sex behaviors and ART adherence among PLH as part of routine clinical care, not as a separately staffed and funded research study. Touch screen tablets containing the CARE+ Kenya program were placed within the adult care HIV clinic modules (1–3) at AMPATH center in Eldoret, Kenya from November 1, 2013 to June 30, 2014. Prior to placing the

tablets in each module, CARE+ Kenya advertisements and information announcing availability of the educational tool were placed in each module. Additionally, clinicians were given referral forms so that they could refer patients whom they thought would benefit from use of this counseling tool; these could include patients newly enrolled in care, newly starting ART, having known non-adherence, or having detectable viral loads while on treatment. Inclusion criteria for this portion of the study were, (1) being in care within the adult modules at AMPATH center, and (2) able to understand spoken Kiswahili or English. Verbal informed consent during this phase of the study enabled tracking of usage data by participants.

Results

We approached 586 individuals at the two study sites; 236 consented (40% acceptance); 236 were randomized and completed baseline assessments, and 95% (225/236) were retained for the 9-month RCT study duration (Figure 2).

There were 236 participants who had complete data for log₁₀ viral load at baseline; and at month 9, only 222 participants had complete data for this outcome variable. At baseline the sample size for the control arm was equal to that of the intervention arm at 118; at month 9, the sample sizes were 109 and 113 respectively; these were the subjects who had data observed for log₁₀ viral load.

Table 1 shows participant characteristics at baseline by study arm. There were no significant differences between the treatment and control group characteristics. Gender distribution and allocation to treatment or control arms also did not differ by clinic sites (BF vs. M1).

During the baseline visit (n=133), 56% (n=66) in the intervention arm vs. 57% (n=67) in the control arm had undetectable VL, compared to undetectable VL measures (n=168) at 9-months, 74% (n=84) vs. 77% (n=84) respectively.

Figure 3A shows that both the intervention and control arm had a > 0.5 log₁₀ reduction in VL over time. This finding is clinically relevant and statistically significant ($p=0.0007$). Viral load for both intervention (0.96, SE=0.16 vs. 1.54, SE=0.18) and control arms (0.80, SE=0.15 vs. 1.34, SE=0.16) were significantly lower at 9-months than at baseline (data not shown). Figure 3B shows decreases in VL over time for both arms and suggests an effect modification by sex; while intervention effect was not statistically significant for either sex, log₁₀ viral load at 9-months coefficient were in opposite directions, 0.17 among males and -0.12 among females.

In terms of ART adherence outcomes, measured by eCAPs, pharmacy refill, self-report (7-day missed dose and 30-day VAS) and sexual risk behavior outcomes, the results showed non-significant differences between treatment and control groups (data not shown). One notable finding was that the self-reported VAS levels of adherence captured by the CARE+ Kenya program were significantly higher than those captured by the eCAP electronic monitoring for all 3, 6, and 9-month sessions (VAS: 64%, 62%, 60% vs eCAP: 31%, 31%, 34%; $p < 0.0001$).

CARE+ Kenya Computer-based Counseling Program

Overall, a majority of participants reported a positive experience with the CARE+ Kenya program, with 93% reporting that it was easy/very easy to use the computer tablet, 75% reporting that CARE+ Kenya sessions were just right (not too long or too short), and 84% percent reporting that they had enough privacy during the sessions. When asked if they were to do this again, which type of counselor would they prefer, 76% selected computer-based counseling rather than face-to-face with a health care provider. Ninety percent of participants said that the CARE+ Kenya session helped them, compared to face-to-face counseling. However, 62% responded “yes” when asked if they needed further face-to-face counseling. Acceptability of the CARE+ Kenya program did not differ by gender but did differ by clinic site. Fifty-two percent of participants from the urban clinic site (M1) reported that the counseling tool was easy/very easy to use, compared to 40% from the rural clinic site (BF), $p=0.024$. Overall, these findings agree with the themes that emerged from the focus group sessions (data not shown). A total of 86 participants took part in the focus groups; 42 participants (32 females and 10 males) enrolled in M1 and 44 participants (37 females and 7 males) enrolled in BF. Demographics of focus group participants is consistent with those reported for the RCT (data not shown). Overall, participants liked that use of the computer was informative regarding how to live positively with HIV and provided confidentiality, and privacy. Additionally, focus group participants mentioned that the tool was very easy to use; and participants appreciated that they can follow the information on the screen while listening to the audio in either English or Kiswahili language narration choice options. More importantly, majority (88.7%) were in agreement that the tool can be easily used by other people.

Implementation Phase

Following the RCT, the CARE+ Kenya tool was made available to patients at both clinic settings, either by their own initiative or through a referral from a clinic provider. In this phase, during which the tool was available for use but no study incentives or specialized study staff engagement was provided, the following insights were gained. One, both patients and staff mentioned the lack of financial incentives or “motivators” as a barrier. Two, patients often gave time constraints as a reason to not engage in using the tool, or in ending a session early. The issue of stigma also came up in this context, with the stated goal of wanting to get in and out of the clinic as quickly as possible to avoid being recognized by people. Technological problems including intermittent loss of connection to the server and other network problems was an issue. Finally (and perhaps unsurprisingly), some providers expressed the concern that the computerized counseling tool could possibly threaten their job, rendering their role “useless”.

Discussion

Principal Results

This RCT showed that a computer counseling intervention developed in a high-income country setting could be adapted and delivered effectively in a low-income, high-volume and HIV burden setting in sub-Saharan Africa. The intervention provided by the computer ensured that evidence-based counseling was delivered to patients without need for scarce

staff time. Both the full intervention and the control arms showed reduced viral load and improved risk behaviors over time. This may suggest that merely assessing risk behaviors through questionnaires on the computer had some behavioral impact, and that longer sessions that included MI-based risk reduction plans, skill-building videos, etc. do not effectively add more focused behavioral impact.

Limitations and Strengths

A strength of our study was the availability of different sources of ART adherence monitoring data. We were able to limit reporting bias by confirming participant self-report of medication regimen adherence by VAS from the CARE+ Kenya program with ART refill data from AMPATH's pharmacy database, clinic staff pill counts during visits, and electronic monitoring which records the date and time the participant opens and closes their eCAP medication bottles. Another strength was the inclusion of both an urban and rural setting within a single care system, thereby minimizing bias since treatment algorithms were harmonized throughout AMPATH. Real-world implementation of CARE+ Kenya counseling tool from a research to a "clinical care" activity phase enabled assessments of satisfaction with the tool in a high volume clinical care setting.

There were several study limitations. Despite the strengths of design described above, certain factors may have limited our ability to detect differences between our intervention and control groups. Participants praised the computer tool and discussed this with other patients. It was not uncommon during the study for other patients to come and ask to be allowed to use the tool because of information they had heard from participants. If participants were also sharing knowledge they gained from using the tool with patients in the control group, then the ability to accurately measure differences in outcomes would be diminished. In addition, the RCT was conducted in an ongoing HIV care system where providers and staff were also delivering adherence messages to patients at their scheduled medical and pharmacy visits. It was impossible to control for this, and this may have also affected our ability to accurately measure small differences between groups.

Finally, this was an RCT conducted in western Kenya in one rural and one urban hospital-based clinic. While the team was able to demonstrate feasibility, adaptability and implementation of a computer counseling tool in this setting, limitation is that the findings may not be generalizable or easily implemented in some other settings or cultures. Additional adaptation and implementation in various settings among different cultural groups would be helpful to uncover additional barriers that need to be addressed.

Conclusions

A computer-based counseling tool adapted for use in East Africa can address health workforce deficits, is feasible and acceptable to implement in a high-volume HIV setting and provides evidence-based ART adherence and risk reduction support. The results showed that both the control and the intervention arms had a reduction in log10 viral load over time and that the drop was statistically significant; the effect of the intervention had a positive impact on study participants viral load reduction. This trial did not suggest that inclusion of in-depth content such as skills-building videos and risk reduction plan adds behavioral ART

adherence effect beyond simple ACASI risk assessment. Ongoing implementation of such a tool, if made part of routine clinic services, may need to address provider concerns, patient stigma and time constraints, and technological support.

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Figure 1.
Screenshots of CARE+ Kenya

Figure 2.
 Participant flowchart of the CARE+ Kenya program, four sessions over 9 months.

Figure 3.
(A) Log10 viral load over time stratified by group. (B) Average log10 viral load stratified by group and sex.

Table 1.

Demographic characteristics of CARE+ Kenya intervention and control groups (N=236), including outcomes of interest

Variable	TOTAL	CARE+ Kenya (n = 118)	CONTROL (n = 118)	P
Clinic location, n (%)				
Burnt Forest (rural)	-	54 (46)	55 (47)	0.896
Module 1 (urban)	-	64 (54)	63 (53)	
Sex, n (%)				
Male	-	29 (25)	22 (19)	0.268
Female	-	89 (75)	96 (81)	
Age in years, mean (SD)	-	37 (8.6)	38 (7.7)	0.783
Married/living together, n (%)	-	55 (52)	58 (52)	0.988
Education, n (%)				
None	-	10 (8)	12 (10)	0.394
Some primary education	-	61 (52)	68 (58)	
Some secondary education	-	26 (22)	14 (12)	
Completed secondary education	-	17 (14)	18 (15)	
College/University	-	4 (3)	6 (5)	
Occupation, n (%)				
Farming	-	30 (28)	35 (32)	0.921
Business	-	31 (29)	33 (30)	
Employment	-	43 (41)	40 (36)	
Sex business	-	2 (2)	2 (2)	
Disclosure, n (%)				
Disclosed HIV status to main partner	-	44 (85)	45 (82)	0.699
Disclosed HIV status to other partner	-	8 (57)	13 (57)	0.970
Substance use behavior, n (%)				
Alcohol use in last 3 months	-	34 (32)	31 (27)	0.452
Drug use	-	23 (19)	16 (14)	0.220
Smoking	-	15 (13)	11 (9)	0.367
Injecting drug use in last 3 months	-	5 (4)	3 (3)	0.496
Sexual behavior, n (%)				
Any sex	112 (52)	56 (51)	56 (53)	0.778
Condom use	69 (32)	34 (31)	35 (32)	0.921
Condom use with problems	193 (82)	97 (82)	96 (81)	0.866
Discordant sex with main partner	21 (9)	9 (8)	12 (10)	0.493
Discordant sex with other partner	1 (0.4)	0 (0)	1 (0.4)	1.000
Adherence VAS, n (range)	92 (78–99)	90 (71–99)	95 (88–99)	0.139
VAS Scale 95%, n (%)	99 (45)	44 (41)	55 (50)	0.189
Log10 HIV-1 viral load, mean (SD)	1.46 (1.81)	1.56 (1.91)	1.36 (1.70)	0.391
Undetectable viral load, n (%)	-	66 (56)	67 (57)	0.896
Told had STI other than HIV in past 3 months, n (%)	-	27 (24%)	23 (20)	0.500

Variable	TOTAL	CARE+ Kenya (n = 118)	CONTROL (n = 118)	P
Positive for <i>Chlamydia</i> , n (%)	-	2 (2)	2 (2)	1.000
Positive for <i>Gonorrhea</i> , n (%)	-	3 (3)	3 (3)	1.000
Positive for <i>T. vaginalis</i> , n (%)	-	4 (3)	9 (8)	0.253
Missed clinic visit [*] , n (%)	-	83 (70)	76 (64)	0.331

Comparison by Fisher exact test, two-sample t-test, or Wilcoxon rank-sum test;

^{*} defined as coming to clinic 7 days before or after the appointment date