Final Report

Evaluating the Effectiveness of Patient Education and Empowerment to Improve Patient-Provider Relationships and Clinical ART Outcomes

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
BMI	Body Mass Index
CD4	Cluster of Differentiation 4
CDC	Centers for Disease Control and Prevention
CI	Confidence Interval
GNI	Gross National Income
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
ICRC	International Clinical Research Center
ID	Identification
I-TECH	International Training and Education Center for Health
ITT	Intention to Treat
IQR	Interquartile Range
MoHSS	Ministry of Health and Social Services
OGAC	Office of the U.S. Global AIDS Coordinator
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan for AIDS Relief
PHE	Public Health Evaluation
PI	Principal Investigator
PLWHA	People Living with HIV and AIDS
RIAS	Roter Interaction Analysis System
SD	Standard Deviation
STI	Sexually Transmitted Infection
TB	Tuberculosis
UK	United Kingdom
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UW	University of Washington
WHO	World Health Organization

ABSTRACT

Background: Working with patients to be more active participants in their specific interactions with their health care providers has been shown to improve the effectiveness of health care consultations for HIV-related encounters. This report describes an impact evaluation of a patient education and empowerment training program implemented in Namibia for patients on antiretroviral therapy (ART) which was designed to improve patient/provider communication and patient clinical outcomes.

Design and Methods: In order to increase patients' active engagement during patient-provider interactions, we developed and implemented patient training sessions in 4 ART clinics in Namibia using a "Patient Education and Empowerment" training curriculum. We tested the effectiveness of this intervention in a randomized controlled trial of 589 patients. At 4 separate clinical sites, newly initiating ART patients were enrolled, with half of those patients randomly assigned to immediately receive 3 sessions of the training and another half to receive the training 6 months later. The effects of the training on patient engagement during medical consultations were measured at each clinic visit for a minimum of 8 months of follow up by audiotaping and coding the consultation with the provider. Patient-provider communication was measured using a validated method for describing medical dialogue, the Roter Interaction Analysis System (RIAS), in addition to a global affect scale. RIAS outcomes were compared between intervention and control groups at 6 months. Clinical outcomes associated with the trainings, such as changes in body mass index (BMI) or cluster of differentiation 4 (CD4) count, were compared at 6 and at 12 months. A mixed effects regression model was used in the analysis.

Results: 299 newly-initiating ART patients (of whom 195 (65%) were female) were enrolled in the intervention group and 290 newly-initiating ART patients (of whom 199 (69%) were female) were enrolled in the control group. The average time since HIV diagnosis for each group was 17.1 and 19.7 months, respectively. At 4-8 months post enrolment (the window for the 6 month time point) using Intention to Treat (ITT) analysis, consultations in the intervention group had statistically significant higher RIAS scores in doctor facilitation and patient activation (adjusted difference in score 1.16, p=.005, CI=.35,1.96), doctor information gathering (adjusted difference in score 3.08, p=.000, CI=1.47,4.69), patient question asking (adjusted difference in score .45, p=.013, CI=.09,.80), and patient positive affect (adjusted difference in score 2.24, p=.002, CI=(.85,3.63). Doctor affect was also statistically significantly higher in the intervention group when measured using the global affect scale (adjusted difference in score .52, p=.04, CI=.02,1.01). No clinical outcomes, measured at 6 and 12 months of follow up, were statistically significant.

Discussion: Increased engagement of patients in clinical consultation can be achieved via a targeted training program integrated into ART clinics so that the trainings complement other services being provided. The longitudinal design of this particular study allowed for measurement of communication and clinical changes over time. Randomizing the intervention allowed us to better isolate the effects of the training among the diverse populations and locations in Namibia. Given the important role of communication in patient adherence and to satisfaction with care, RIAS coding methods and other methods designed to measure the quality of patient-provider interactions should be used more in research in countries with high HIV/AIDS burden.

INTRODUCTION

In Namibia, HIV care and treatment training of health care workers (HCWs) includes an emphasis on "patient centeredness", encouraging HCWs to elicit patient concerns. Through conversations with MoHSS leaders, observations of clinicians in ART clinics, routine reporting data and informal conversations with PLWHA leaders, it became clear that in spite of HCWs' best efforts, many patients were minimally engaged in their clinical consultation, providing only abbreviated responses to HCW inquiries, initiating few questions, and articulating few concerns about their treatment. A range of barriers were theorized to inhibit HIV patient active participation in their care, including health literacy, language limitations, normative doctor patient expectations, historical contexts, and power differentials. We hypothesized that addressing some of these issues through patient education and empowerment trainings would impact the quality of care that HIV positive patients receive - both real and perceived - and ultimately improve adherence and clinical outcomes.

The findings of this study show tangible benefits to both patient and doctor after the trainings, providing evidence that education and empowerment actions can immediately and positively influence the quality of care provided at the ART clinics.

BACKGROUND

Namibia has made remarkable progress in the rollout of ART services to HIV positive persons in need of treatment. The provision of ART in public sector health facilities in Namibia started in 2003 and a subsequent rapid scale-up of ART services led to coverage approaching Universal Access targets[1]. According to a 2012 United Nations General Assembly Special Session on HIV/AIDS (UNGASS) report, 67 percent of adults and 75% of children with advanced HIV infection (meeting World Health Organization (WHO) criteria) in Namibia are receiving ART or a total of 92,000 persons by mid-2011[2]. Additionally, Namibia's adoption of new WHO ART guidelines, which advocate for starting HIV treatment sooner, has led to increasing numbers of individuals eligible for HIV care and treatment. Given the new WHO criteria and new infections, the number of people in need of ART is expected to rise to approximately 150,000 in Namibia by 2016[2]. With such rapid scale-up of services, the MoHSS is interested in quality of HIV care and understanding the factors associated with the effectiveness of HIV treatment support programs.

It has been shown that patient-provider interactions can impact retention in ART treatment and adherence. Three Cochrane reviews lend support for adherence interventions that include improving patient-provider interaction.[3-5] In the United States, clinical training of HIV health care providers has thus emphasized the importance of active listening and patient active participation as key to increasing the quality and effectiveness of the patient-provider encounter.[6-9] Active listening helps the clinician better hear and understand patient physical and psycho-social concerns and complaints and, hence, more effectively respond to them. Active listening also involves the skilful use of probes to put patients at ease and elicit information that will guide clinical advice and treatment. Finally, active listening skills on the part of the provider can encourage patient participation and feelings of empowerment in their own care and treatment.[6-9]

Despite the number of interventions that involve training physicians, few intervention trials have sought to train patients to engage more fully in the health care process.[10] The majority of communication studies involving patients are designed to assess medical communication largely as a physician monologue with only occasional attention to the individual patient's own response.[11-17,18,19] Few studies focus on the role of the patient or patient companion during medical visits, or on ways a patient can be empowered to become more engaged in his or her treatment process.[20]

This PHE sought to determine the effects of patient empowerment training on patient active engagement during medical consultations in 4 different ART clinics in Namibia. A brief physician training in active listening was included as part of the overall intervention, to ensure that clinical staff had some exposure to the theoretical benefits of patients actively engaging in their clinical consultations. The effects of the training on patient engagement during medical consultations were measured using a validated method for describing medical dialogue, the RIAS.[18] Potential clinical outcomes associated with the trainings were also measured in the study, as a secondary research aim.

METHODS

Study Design

We used a quasi-experimental, prospective longitudinal design to evaluate the effectiveness of the patient education and empowerment training intervention. Newly initiating ART patients at each study site who were eligible and gave informed consent were recruited into the study. At each of 4 ART clinic facilities, consented patients were then randomly assigned to the intervention (Group 1) or delayed intervention (Group 2) group. Data from the 2 groups from each site were aggregated and compared by group to assess the immediate and longer-term effects of training patients in active participation in their own clinical care. Comparisons were made between and within intervention groups at baseline, 6 months and 12 months. All health care providers were blinded to the degree possible to group assignment. Study coordinators and other staff were not blinded. At 6 months differences in patient engagement with their health care providers, between intervention and comparison groups, were analysed and at 12 months differences in health outcomes were analysed. A total of 589 participants were enrolled into the study out of the 592 enrolment target (Figure 1).

The 4 ART clinics were purposively selected in association with the MoHSS as study sites in order not to conflict with or confound on-going research being conducted by other entities. Every effort was made to choose comparable sites in terms of number of patients on ART, number of doctors and nurses, and number of newly initiating ART patients each month. At the same time, facilities from different regions were selected to better understand the variability of intervention implementation and results. Katima Mulilo (Caprivi Region), Rundu (Kavango Region), Onandjokwe (Oshikoto Region), and Katutura Health Centre (Khomas Region) were the selected sites. These facilities had patients with similar characteristics, comparable infrastructures, routine collection of the proposed outcome measures, systems that can support studies conducted at the facility, and are easily accessed. Each site was asked to enrol 148 participants; 74 in the intervention group and 74 in the comparison group.

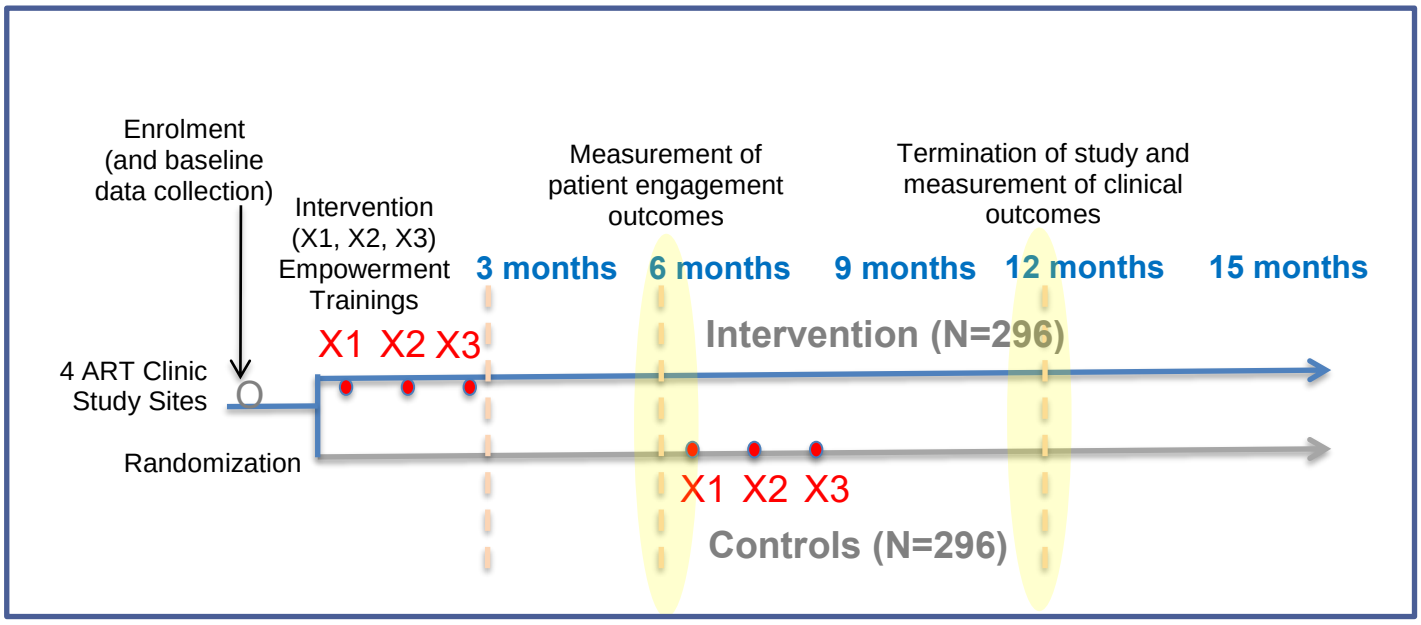

Figure 1: Study Randomization, Intervention and Follow Up

Study Sites and Personnel

Training of 4 study coordinators occurred in November and early December of 2011. Study sites were opened in December of 2011 and were actively recruiting study patients and collecting data until July 2013. Other activities at the sites January-March of 2012 included 1) training of trainers in the Patient Education and Empowerment Curriculum, 2) training of health care personnel in active listening and 3) a routine site monitoring visit in March of 2012. Each site subsequently hired research assistants so that each site included a site coordinator, trainer and research assistant. Sites were monitored every quarter starting in March 2012.

Data Collection Methods

Recruitment and Enrolment of Patients:

Study coordinators approached patients in the waiting room at the ART clinics. Each clinic has dedicated days of the week for newly initiating ART patients. Coordinators screened the patient for interest in participation, age (≥18 years old), treatment status (newly initiating ART), planned main point of care (including verifying their residence was within a reasonable distance from the facility), and time availability to answer questions and complete the 3 trainings. If the above criteria were met, the coordinator assigned a screening ID to the patient and then proceeded to start the informed consent process. A standard set of locator information was collected at time of enrolment and updated at each visit.

Recruitment and enrolment activities continued in this manner until the desired sample sizes for patients in each arm of the study had been achieved. Some sites over- or under-enrolled depending on the success of recruitment. An in-depth log was kept on the number of patients approached, number of patients screened, number of patients enrolled and those screened that did not enrol.

Randomization:

Once enrolment data was collected, the patient was randomized to Group 1 or 2 and given a unique study ID number. Envelopes with the study ID number, and randomly allocated group assignment, were opened only at the time of randomization of each new enrolled patient. Group assignment was noted in the patient enrolment log held by the study coordinator. Patients were asked to not disclose information about the intervention to other ART patients. Group 1 was the intervention group. Group 2 was the delayed intervention group who received the intervention 6 months after Group 1.

Outcome Measurement:

Once enrolled in the study, outcome measures were collected at each clinic visit from both patients and providers for the duration of the study. Clinical outcomes were collected for each enrolled patient through abstraction of patient charts at the hospital (Table 1).

To measure the impact of the intervention on patient-provider interactions, we used RIAS, an evidence-based communication, education, research and practice tool[29]. The method has been tested for validity and reliability many times over in various clinical situations and has shown great coding adaptability to various types of interaction, resource specific settings, and disease specific interventions. RIAS was used to measure the amount of patient engagement with their health care provider, the main outcome for the study. Each follow-up clinic visit for all patients enrolled in the study was audio-taped and coded using RIAS coding methodologies and RIAS software. If any interpreters were present during the consultation this dialogue was also coded. In addition to RIAS medical codes, additional codes were developed and logged in coding books based on local context and language use. Study coordinators at each site were trained extensively to listen to

the medical dialogue in each recorded consultation and code appropriately. Periodic reliability studies were performed, using English language audio-files, to determine inter-coder reliability. Weekly coding calls were organized to support the coding work at the study sites and to reach consensus on how different utterances, from either the patient or the physician, should be coded. When decisions were made about how to code utterances, these coding norms were added to the coding logbooks. Some additional process monitoring of the trainings was conducted for quality assurance.

In addition to RIAS coding, study coordinators assessed each clinical consultation for global affect using a standardized scale that indicates subjective measures of overall doctor and patient affect during the consultation. Examples of global affect that are coded are physician dominance, patient and physician interactivity, patient and doctor anger and upset and patient and doctor empathy and friendliness. Global affect scales have been developed and validated in many studies and settings by the same study team that developed RIAS.

Other outcomes include patient satisfaction with the care they have received from their providers, and the provider's perspective on the patient's level of engagement. To measure these outcomes, health care providers were asked to complete a brief one-page consultation assessment form after each consultation with a participant enrolled in the study. The consultation assessment form was brief to ensure that clinicians were able to complete it immediately after each interaction with an enrolled participant for the duration of the study. The questions asked about provider perceptions of participant involvement during the consultation. Participants enrolled in the study were also asked to complete a brief consultation assessment form after each clinical consultation. This survey included some open-ended questions designed to elicit more in-depth participant perspectives on the clinical consultations and was designed to measure, among other outcomes, participant capacity to manage their HIV disease.

As noted, to measure clinical outcomes, data was extracted from study participant medical charts at baseline, and then on a quarterly basis for the duration of the study to document adherence to care and treatment and health outcomes. The following data points were extracted: WHO clinical stage at initiation of ART (and any further staging that occurs); fulfilled and missed consultation appointments; fulfilled and missed pill pick-up; CD4 count; BMI (calculated); treatment regimen; and recorded diagnosed opportunistic infections (OIs) (tuberculosis (TB), sexually transmitted infections (STIs), etc.) and referrals for OIs.

Data Collection Summary

Table 1: Summary of Study Data Collected

Site	# Enrolled	Enrolment Forms	Total RIAS Recordings	Total Patient Exit Interviews	Total Provider Exit Interviews	Mean # Clinic Visits Abstracted
Windhoek	199 (100 I*/99 C)	199	718	666	834	12 Clinic Visits
Rundu	169 (86 I/83 C)	169	579	386	424	6 Clinic Visits
Onandjokwe	115 (55 I/50 C)	115	354	445	529	6 Clinic Visits
Katima	106 (58 I/58 C)	106	195	294	284	6 Clinic Visits

*I=Intervention, C=Control

Data Analysis

Data related to patient demographics were gathered from patients in both groups at enrolment and compared between the trained Group 1 and the untrained Group 2. The coded audio-tapes in RIAS were quantified and frequencies and overall composite scores for all categories calculated. Global affect scores for both doctor and patient were analysed.

RIAS and global affect outcomes were compared at 6 months (using a 4-8 month window) between Groups 1 and 2 to test the post-intervention quality of patient/provider interactions (e.g., frequency of provider initiated utterances, frequency of participant initiated utterances, and length of consultation). A mixed affects model was used for the regression, with adjustment for site, length of consultation, nurse vs. doctor, provider, provider sex, patient gender, and whether an interpreter was present. To examine longer term impact of the intervention on health outcomes, clinical outcomes were compared between Groups 1 and 2 at twelve-months. We applied an intention-to-treat approach in this analysis, considering all available observations provided by participants.

Tables were produced showing means and results of statistical tests between groups at each time point. Unadjusted comparisons at a given time point were performed with a simple t-test. Adjusted comparisons were made using standard linear regression, adjusting for potential confounders.

Since ART clinic visits occur approximately quarterly, windows around 6 months and 12 months were defined to specify which observations in follow-up contributed to the 6-month and 12-month analyses. For "6-month" analyses, we used measurements taken between 4 and 8 months. For "12-month" analyses, we used all observations available at 12 months and later. These time windows resulted in more than one observation per person identified for analysis at a given time point. Nevertheless, we used all the observations in the analysis by using linear mixed model methodology in the linear regression, with random effects to account for correlation in repeated measures on the same person. A random effect for clinician (using a provider ID) was also included to adjust for correlation in measures taken from participants seeing the same clinician.

Study Limitations

It is possible that some cross group contamination occurred between the two groups. Patients in Group 1 (the intervention group) could have had friends or family in Group 2 (the delayed intervention group). Also, many ART clinics in Namibia have a designated "new patient initiation" day once a week where all ART eligible patients will come to start treatment. These new patients also share similar (sometimes identical) follow up schedules. As these "new patients" included both intervention and control patients, there is the possibility that during follow up visits the intervention patients coached control patients in how to be empowered during their consultations. We tried to reduce this possible contamination by reminding patients that their study group and the content of the trainings were confidential.

There is also the possibility of contamination of patients in the control group due to inadvertent "coaching" by health care providers before the patients in that group were trained. This possibility was reduced by blinding providers to group identification as much as possible and by holding trainings out of the health care provider's view. The study team observed that most providers were too busy to discern the study group of the patient and even if they did have some interest in this it waned as the study proceeded.

Further bias could have been introduced by the coding of RIAS by the site coordinators, who were knowledgeable of the group assignment for each participant. This bias was mitigated by keeping the

participant log and training log locked away in a cabinet, especially during coding work. Still, it is possible the coder sometimes remembered the group assignment and this influenced coders' work.

The study was based in 4 purposively selected healthcare facilities and not a randomized sample. This decision was made to increase feasibility of the intervention evaluation within the budget, time and local implementation constraints. As a result, it does not allow the results to be generalized to the wider population of ART patients in the country. However, given that the study was randomized and controlled, and that site was adjusted for in the analyses, the results are very important to consider in terms of the feasibility and potential applicability for other facilities in Namibia.

Finally, there may be impact from missing data in the study – from either patient loss to follow up or by study team members' 'missing' a patient's follow up visit in the clinic. In examination of this impact we concluded that both the control group and intervention group were missing data in a roughly equivalent manner. In addition, much of missing data occurred not because of loss to follow up but because a study procedure was missed during a patient clinic follow up visit. These missed procedures tended to occur at random due to the challenge of follow up of patients during the study and not because of study group, providing further evidence that the missing data in the study was missing at random. Even so, the reduced power due to missing data made it more difficult to detect differences between the two study groups.

FINDINGS

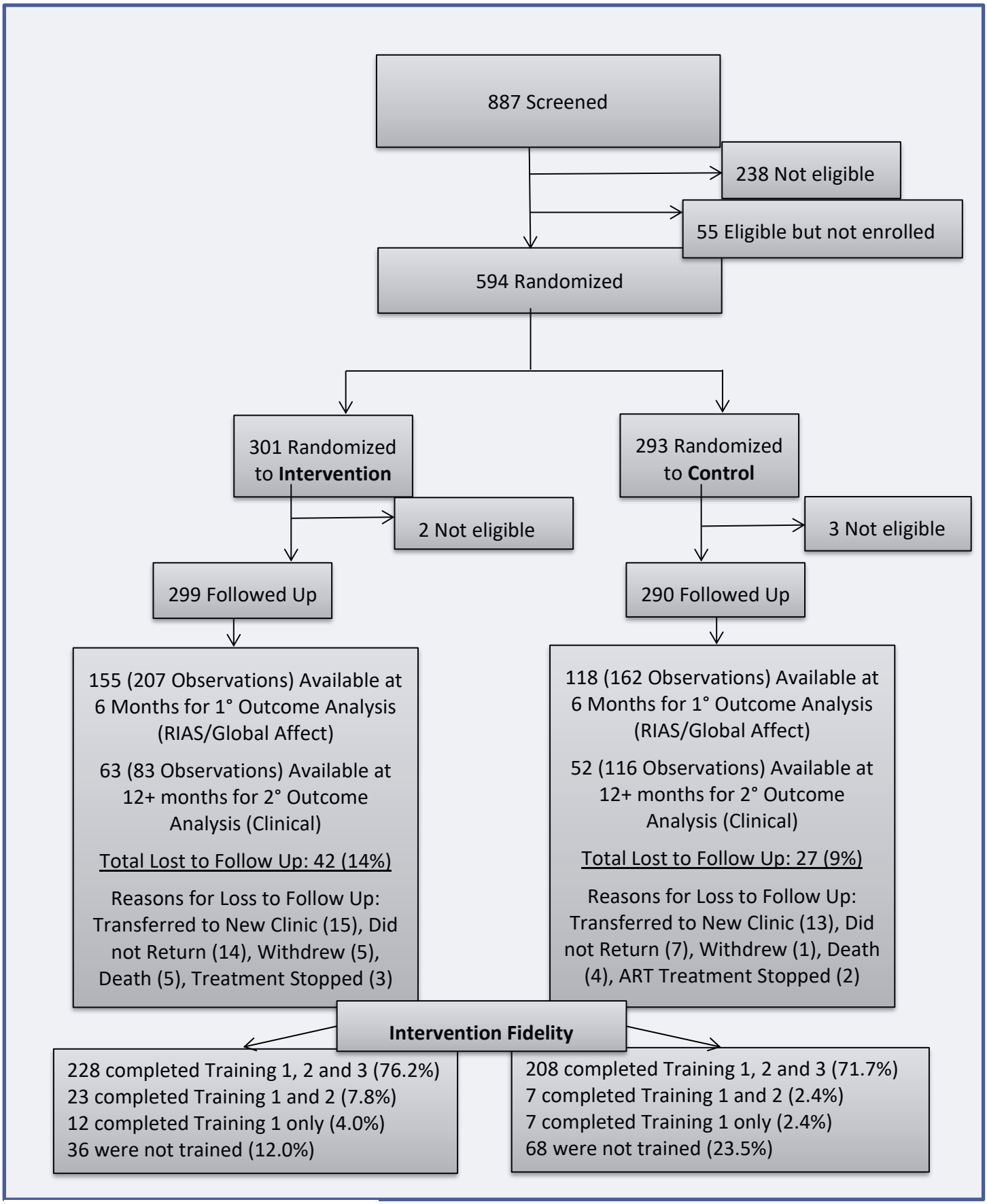

Figure 2: PHE Namibia Study Cascade

Baseline

The demographic characteristics of the study population varied considerably by site (Table 2) but not by study arm (Table 3). Most participants in the study were female (67%) and this was especially high at the Rundu site (78% female). Employment was highest in Windhoek, at Katutura Health Centre, with 53% of the participants stating that they were currently employed. Katima participants reported the highest educational levels, with 79% having gone to Secondary school compared to 66% overall in the study. Marital status varied

Table 2: Baseline Characteristics of Study Population by Study Site

Participant Characteristic	Katutura Health Centre	Rundu	Katima	Onandjokwe	Total
N enrolled	199	169	115	106	589
Demographics					
Female gender	116 (58%)	132 (78%)	77 (67%)	69 (65%)	394 (67%)
Age – mean (SD)	35 (8.5)	32 (6.7)	34 (8.5)	35 (8.6)	34 (8.0)
– median (IQR)	34 (29-40)	31 (27-36)	34 (28-40)	34 (29-41)	33 (28-39)
Employed	106 (53%)	53 (31%)	11 (10%)	40 (38%)	210 (36%)
Education					
None	15 (8%)	7 (4%)	1 (1%)	7 (7%)	30 (5%)
Primary	59 (30%)	47 (28%)	23 (20%)	34 (32%)	163 (28%)
Secondary	118 (59%)	112 (66%)	91 (79%)	65 (61%)	386 (66%)
Post-Secondary	7 (4%)	3 (2%)	0 (0%)	0 (0%)	10 (2%)
Marital Status					
Single	114 (57%)	82 (49%)	45 (39%)	68 (65%)	309 (53%)
Married	34 (17%)	16 (9%)	55 (48%)	13 (12%)	118 (20%)
Separated or Divorced	1 (.5%)	2 (1%)	7 (6%)	6 (6%)	16 (3%)
Widowed	1 (.5%)	7 (4%)	7 (6%)	4 (4%)	19 (3%)
Live with Partner (Unmarried)	49 (25%)	62 (37%)	1 (1%)	14 (13%)	126 (21%)

Participant Characteristic	Katutura Health Centre	Rundu	Katima	Onandjokwe	Total
Reproductive characteristics					
Using family planning method (women)	41 (36%)	68 (51%)	43 (56%)	28 (41%)	180 (46%)
Pregnant (women) Yes Don't know	 18 (16%) 1 (1%)	 34 (26%) 6 (5%)	 3(4%) 0 (0%)	 8 (12%) 2 (3%)	 63 (16%) 9 (2%)
Live births (women) Mean (SD) Median (IQR)	2.0 (1.4) 2.0 (1-3)	1.8 (1.3) 2.0 (1-2)	1.8 (1.6) 2.0 (1-3)	2.8 (2.4) 2.0 (1-3.5)	2.0 (1.6) 2.0 (1-3)
Children (men) Mean (SD) Median (IQR)	3.2 (2.2) 3.0 (1-4)	3.2 (2.1) 2.0 (2-4)	2.4 (1.5) 2.0 (1-3)	3 (2.3) 2.0 (1-4)	3 (2.1) 2 (2-4)
HIV characteristics					
Months since first positive HIV test: -- Mean (SD) -- Median (IQR) Unknown or missing	 14.7 (19.6) 5.7 (1.2-23.3) 19 (9.6%)	 19.7 (26.1) 4.4 (1.4-31.3) 6 (3.6%)	 16.9 (24.3) 3.6 (1.0-25.0) 7 (6.1%)	 24.4 (24.5) 14.8 (2.9-44.2) 3 (2.8%)	 18.4 (23.7) 5.7 (1.4-30.4) 35 (5.9%)
Body Mass Index (BMI) -- Mean (SD) -- Median (IQR) Unknown or missing	 22.3 (3.5) 22.3 (19.8-24.3) 61 (30.7%)	 22.5 (4.0) 22.2 (19.7-24.3) 23 (13.6%)	 21.5 (3.7) 20.7 (18.5-23.9) 41 (35.7%)	 19.7 (3.6) 19.2 (17.3-21.5) 18 (17.0%)	 21.7 (3.8) 21.3 (18.9-23.9) 143 (24.3%)
Weight (kg) -- Mean (SD) -- Median (IQR) Unknown or missing	 59.9 (10.5) 59.0 (54.0-64.5) 23 (11.6%)	 60.6 (11.9) 60.0 (52.9-68.0) 6 (3.6%)	 58.7 (9.8) 58.0 (52.0-64.0) 14 (12.2%)	 56.4 (10.3) 56.0 (49.0-60.0) 1 (.9%)	 59.2 (10.9) 58.6 (52.0-65.0) 44 (7.5%)
WHO clinical stage at ART initiation Stage 1 Stage 2 Stage 3 Stage 4 Unknown or missing	 141 (78%) 14 (8%) 22 (12%) 3 (2%) 19 (9.5%)	 17 (10%) 119 (72%) 26 (16%) 3 (2%) 4 (2.4%)	 55 (50%) 26 (24%) 28 (26%) 0 (0%) 6 (5.2%)	 89 (87%) 10 (10%) 2 (2%) 1 (1%) 4 (3.8%)	 302 (54%) 169 (30%) 78 (14%) 7 (1%) 33 (5.6%)

considerably between sites, with only 9% of participants reporting a 'Married' marital status at Rundu site compared to 12% at Onandjokwe site, 17% at Katutura Health Centre and 48% at Katima Mulilo. The number of women reporting pregnancy at baseline was highest at Rundu site (26%), lowest at Katima site (4%) and 16% overall for the study. Considering health status at baseline, study patients overall seemed to be most unhealthy at the Onandjokwe site, with a longer time period living with HIV before treatment (mean of 24 months), a lower mean BMI than any other site (19.7) and the lowest overall mean weight (56.4 kilos). The WHO clinical stage reported for each site varies considerably and it is probably that use of staging criteria is not uniform across the 4 sites in the study (Table 2).

Table 3: Demographic Characteristics of the Study Population by Study Arm

Participant Characteristic	**Intervention**	**Control**
Demographics	N=299	N=290
Female gender	195 (65%)	199 (69%)
Age – Mean (SD) – Median (IQR)	34 (8.1) 33 (29-39)	34 (8.2) 33 (28-39)
Employed	110 (37%)	102 (35%)
Education None Primary Secondary Post-Secondary	 16 (5%) 83 (28%) 196 (66%) 4 (1%)	 14 (5%) 81 (28%) 190 (65%) 6 (2%)
Marital Status Single Married Separated or Divorced Widowed Live with Partner (Unmarried)	 155 (52%) 67 (22%) 7 (2%) 10 (3%) 60 (20%)	 153 (53%) 53 (18%) 9 (3%) 9 (3%) 66 (23%)
Reproductive characteristics		
Using family planning method (women)	93 (48%)	87 (44%)
Pregnant (women) Yes Don't know	 28 (14%) 6 (3%)	 36 (18%) 4 (2%)
Live births (women) -Mean (SD) -Median (IQR)	 2.11 (1.72) 2.0 (1-3)	 2.04 (1.63) 2.0 (1-3)
Children (men) -Mean (SD) -Median (IQR)	 3.09 (2.15) 3.0 (1-4)	 2.93 (2.08) 2.0 (2-4)
HIV characteristics		
Months since first positive HIV test: -- Mean (SD) -- Median (IQR) Unknown or missing	 17.1 (22.9) 5.1 (1.3-26.8) 18 (6.0%)	 19.7 (24.4) 6.9 (1.5-33.1) 16 (5.5%)
Body Mass Index (BMI) -- Mean (SD) -- Median (IQR) Unknown or missing	 21.7 (3.7) 21.2 (19.1-23.9) 65 (21.7%)	 21.8 (4.0) 21.5 (18.8-23.9) 77 (26.6%)
Weight (kg) -- Mean (SD) -- Median (IQR) Unknown or missing	 59.2 (10.6) 58.0 (52.1-64.0) 19 (6.4%)	 59.2 (11.2) 59.0 (52.0-65.0) 24 (8.3%)

Participant Characteristic	Intervention	Control
WHO clinical stage at ART initiation		
Stage 1	161 (57%)	141 (51%)
Stage 2	71 (25%)	98 (36%)
Stage 3	45 (16%)	33 (12%)
Stage 4	3 (1%)	4 (1%)
Unknown or missing	19 (6.4%)	13 (4.5%)

Six Months Post-Intervention

For all sites combined and for both study arms RIAS and global affect outcomes were analysed at the 6 month follow up time point. For the purposes of the study these were any clinical consultations from 4 months of follow up (and thus occurring after the training intervention) up to 8 months of follow up. For RIAS outcomes a total of 369 consultations were analysed for this time period from a total of 273 participants (Table 4). For global affect outcomes a total of 358 consultations were analysed for this time period from a total of 269 participants. A mixed effects regression model was used to compare the two groups, first unadjusted and then adjusted for site, length of consultation, nurse versus doctor, provider, provider sex, patient gender, and whether an interpreter was present. For the RIAS outcomes measured, 4 outcomes were statistically significant at the 6 month time point, indicating a statistically significant higher mean in the trained group. The RIAS outcomes for the doctor that were significant were facilitation and patient activation (adjusted difference 1.16, CI=.35, 1.96, p=.005) and doctor information gathering (adjusted difference 3.08, CI=1.47,4.69, p=.000) (Table 4). The RIAS outcomes for the patient that were significant were all patient question asking (adjusted difference .45, CI=.09,.80, p=.013) and patient positive affect (adjusted difference 2.24, CI=.85,3.63, p=.002) (Table 4).

Table 4: 6 Month RIAS and Global Affect Measures by Study Arm

Baseline patient –provider interaction measure	Group 1, Intervention Mean (SD)	Group 2, Control Mean (SD)	Difference in score (95% CI)	P-value	Adjusted Difference (95% CI)	Adjusted P-value
Doctor RIAS variables						
N observations	207	162				
N participants	155	118				
Physician verbal dominance	0.54 (0.12)	0.55 (0.13)	-0.01 (-0.03, 0.02)	0.64	-0.003 (-0.03, 0.02)	0.79
Facilitation and patient activation	5.65 (5.24)	4.46 (3.85)	1.05 (0.24, 1.86)	0.01	1.16 (0.35, 1.96)	0.005
Doctor positive affect	4.23 (4.53)	3.69 (3.73)	0.48 (-0.29, 1.24)	0.22	0.55 (-0.20, 1.30)	0.15
Patient-centeredness	1.17 (0.99)	1.00 (0.99)	0.12 (-.07, .30)	0.21	0.13 (-0.06, 0.33)	0.18
Doctor information gathering	9.69 (9.70)	7.03 (7.06)	2.8 (1.15, 4.5)	0.001	3.08 (1.47, 4.69)	0.000

Baseline patient –provider interaction measure	Group 1, Intervention Mean (SD)	Group 2, Control Mean (SD)	Difference in score (95% CI)	P-value	Adjusted Difference (95% CI)	Adjusted P-value
Patient RIAS Variables						
All patient question asking	1.43 (1.84)	0.97 (1.43)	0.48 (0.11, 0.84)	0.01	0.45 (0.09, 0.80)	0.013
Patient activation and engagement	0.87 (1.31)	0.90 (1.32)	0.08 (-0.19, 0.34)	0.57	0.09 (-0.17, 0.36)	0.500
Patient positive affect	9.10 (8.93)	7.05 (6.58)	2.2 (.80-3.63)	0.002	2.24 (0.85, 3.63)	0.002
Global Affect						
N observations	202	156				
N participants	153	116				
Doctor Global Affect						
Positive affect	10.54 (2.74)	10.03 (2.68)	.50 (.003, .99)	0.05	0.52 (0.02, 1.01)	0.043
Dominance/Assertiveness	3.36 (.69)	3.29 (.71)	.06 (-.05, .17)	0.29	0.07 (-0.04, 0.18)	0.22
Interactivity	3.65 (.72)	3.59 (.73)	.09 (-.04, .23)	0.18	0.11 (-0.02, 0.24)	0.11
Patient Global Affect						
Positive affect	14.62 (3.01)	14.44 (2.93)	.21 (-.30, .72)	0.42	0.24 (-0.27, 0.74)	0.35
Interactivity	3.30 (.86)	3.29 (.82)	.07 (-.08, .21	0.36	0.08 (-0.07, 0.23)	0.28

One additional patient-provider global affect outcome was found to be statistically significantly higher in the trained group. This outcome was doctor positive affect (adjusted difference .52, CI=.02,1.01, p=.043). No other global affect outcomes were statistically significantly different between the two study groups. All patient-provider interaction outcomes, however, are higher in the intervention group. This indicates that perhaps with a larger sample size more of the outcomes would be statistically significant.

As part of the analysis the RIAS and global affect outcomes were also modelled with all observations included from baseline to eight months of follow up. The results of these analyses are depicted in Table 5 and in Figures 3-7. When all observations up to eight months are included, three of the thirteen outcome variables remain statistically significant, indicating statistically significant differences (for these three outcomes) between the two study groups over time and not just in the 4-8 month window. The statistically significant outcomes are the RIAS outcome for doctors: facilitation and patient activation (difference .58, CI=.05, 1.12, p=.03) as well as the RIAS patient outcomes: all patient question asking (difference .27, CI=.05,.49, p=.01) and patient positive affect (difference 1.11, CI=.22,2.00, p=.01) (Table 5). None of the global affect outcomes remained statistically significant when all observations were used. In these analyses none of the slopes for intervention and control arms were statistically significantly different from each other, although several slopes were statistically significantly negative over the time period of the study (Table 5). The exception was patient centeredness, with a positive slope of .04 over time which was statistically significant (p=000).

Table 5: RIAS and Global Affect Outcomes for All Observations from 0-8 Months, by Study Arm

Baseline patient – provider interaction measure	Intervention Slope (95% CI)	Control Slope (95% CI)	Overall slope (95% CI)	P-value	Overall difference between arms (95% CI)	P-value
Doctor RIAS variables						
Physician verbal dominance	-.005 (-.012, .002)	-.005 (-.007, -.002)	-.005 (-.007, -.003)	0.000	-.006 (-.02, .005)	0.25
Facilitation and patient activation	-.26 (-.59, .07)	-.30 (-.45, -.16)	-.28 (-.38, -.12)	0.000	.58 (.05, 1.12)	0.03
Doctor positive affect	.12 (-.16, .41)	.03 (-.10, .15)	.08 (-.01, .17)	0.08	.21 (-.25, .68)	0.37
Patient-centeredness	.05 (-.02, .11)	.04 (.01, .07)	.04 (.02, .06)	0.000	.06 (-.03, .16)	0.20
Doctor information gathering	-.10 (-.78, .58)	-.37 (-.67, -.07)	-.22 (-.43, -.01)	0.04	1.02 (-.09, 2.12)	0.07
Patient RIAS Variables						
All patient question asking	.04 (-.09, .17)	.03 (-.02, .09)	.04 (-.003, .08)	0.07	.27 (.05, .49)	0.01
Patient activation and engagement	-.03 (-.13, .07)	-.04 (-.09, .002)	-.04 (-.07, -.005)	0.02	.09 (-.07, .25)	0.28
Patient positive affect	-.09 (-.69, .51)	-.28 (-.54, -.02)	-.18 (-.36, .007)	0.06	1.11 (.22, 2.00)	0.01
Global Affect						
Doctor Global Affect						
Positive affect	-.21 (-.42, -.004)	-.26 (-.35, -.16)	-.23 (-.30, -.17)	0.00	.25 (-.06, .55)	0.12
Dominance/Assertiveness	-.01 (-.06, .04)	-.002 (-.02, .02)	-.007 (-.02, .007)	0.32	.04 (-.02, .11)	0.21
Interactivity	-.02 (-.07, .03)	-.02 (-.04, .002)	-.02 (-.04, -.005)	0.01	.04 (-.04, .13)	0.30
Patient Global Affect						
Positive affect	-.11 (-.32, .09)	-.08 (-.16, .01)	-.10 (-.16, -.04)	0.002	.32 (-.03, .67)	0.07
Interactivity	-.03 (-.09, .03)	-.04 (-.06, -.01)	-.04 (-.05, -.02)	0.000	.06 (-.04, .15)	0.25

In graphing all 5 outcomes that were statistically significant at the 6 month window, it appears that these measures of patient-provider interactions were relatively high at the start of the study, even higher at one month and then decline over time until the time that the control group is trained at 6 months (Figures 3-7). These measurements are consistent with the clinic visits of patients initiating ART, with longer and more complex consultations with the provider at 2 weeks and again at 6 weeks and shorter and less complex consultations as time goes on. Overall for ART visits, then, the quality of interactions between patient and provider mostly declines each month after ART initiation, regardless of which group a study patient is in (and in fact there are several statistically significant negative slopes shown in Table 5). Still, the effect of the training is clearly shown in these graphs, with the intervention group showing higher scores early in the study and throughout the study until approximately 7-8 months of follow up. The effect of training the control group is also clear, with a rise in communication scores starting at approximately 6 months. The two groups already show differences early in the study because most trainings began at the 14-17 day mark (or even earlier) after initiation of ART and any early RIAS and global affect measures included in at the zero time point (up to one month) are already reflecting the effects of training.

Because the full training intervention was completed in an average of 4 months, it is clear from these graphs that the greatest difference in groups occurs around the 6 month time point. This is consistent with the findings at this time point that are shown in Table 4. The exception is doctor global positive affect, which shows only a slight difference at 6 months and is indeed weakly statistically significant (Figure 7).

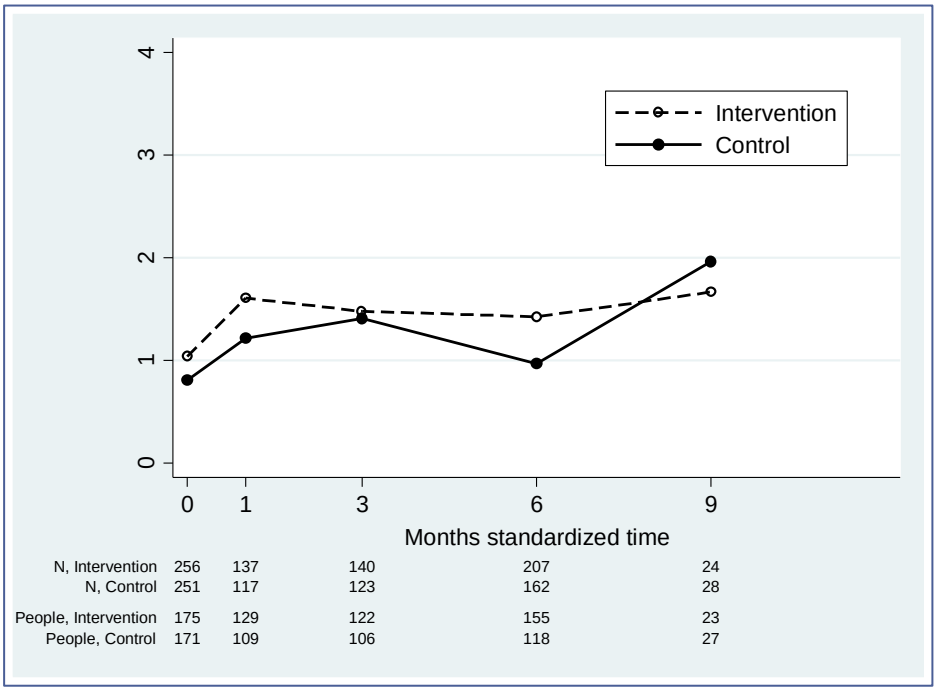

Figure 3: Patient question asking means at key time points

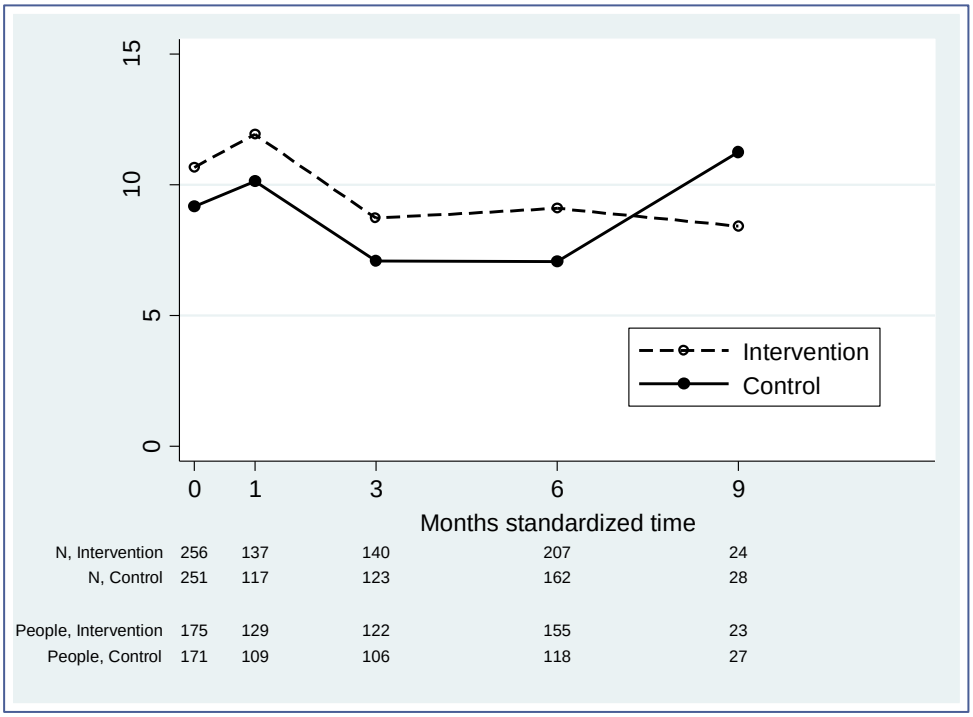

Figure 4: Patient positive effect means at key time points

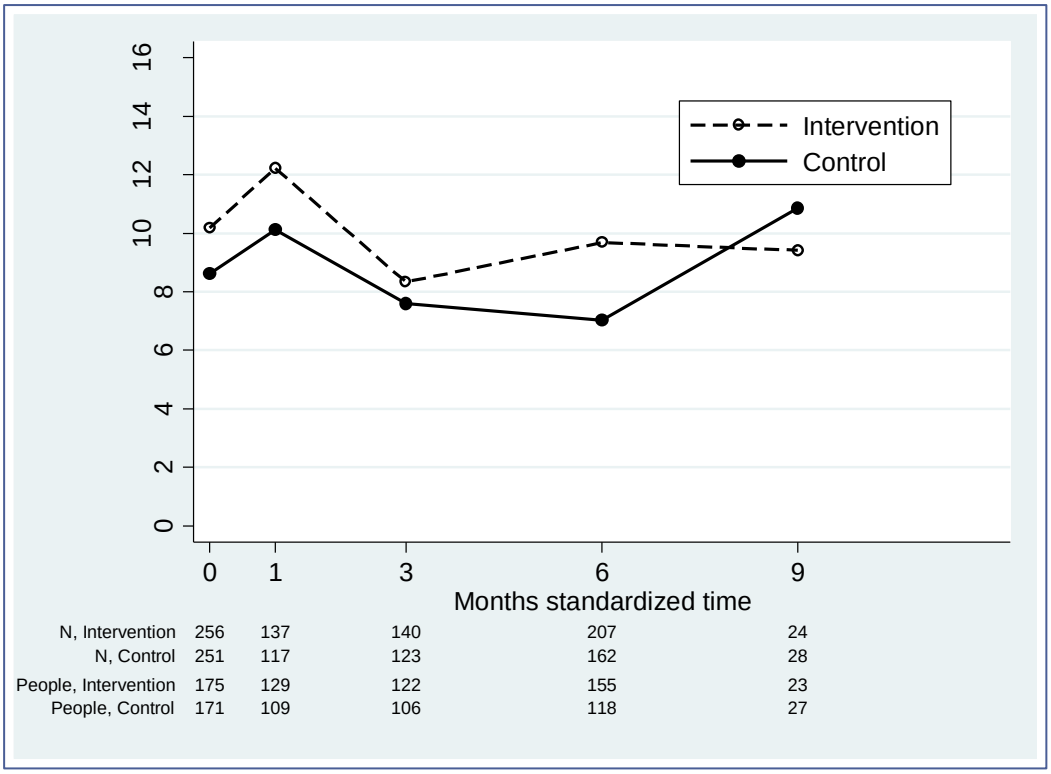

Figure 5: Doctor information gathering means at key time points

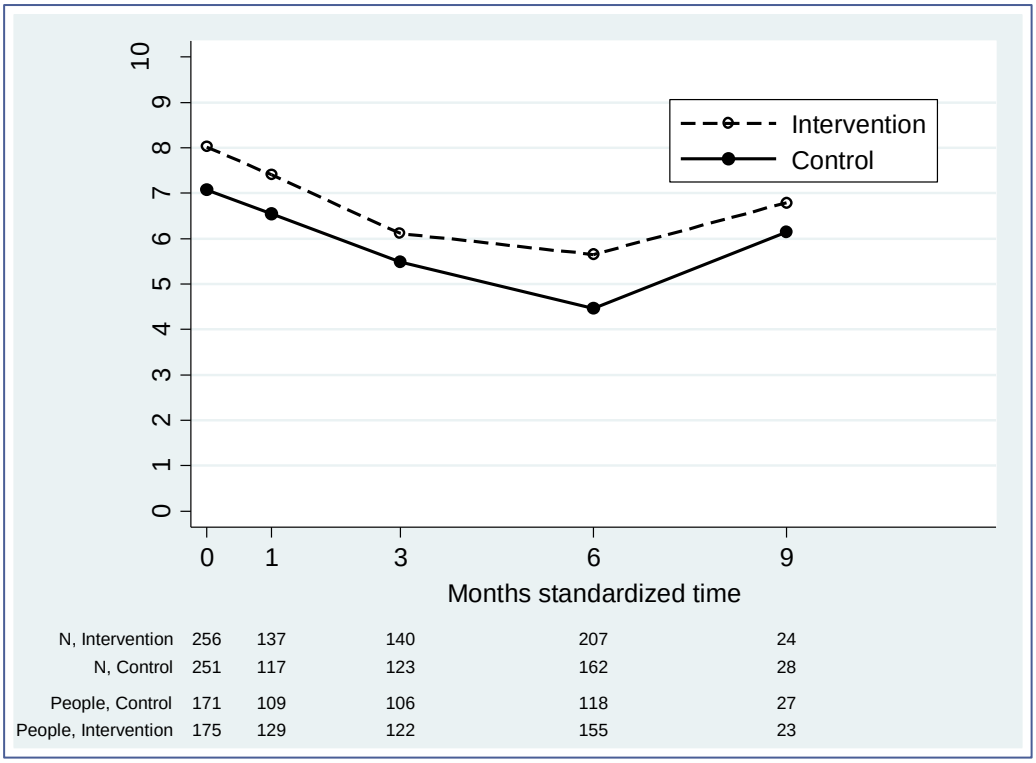

Figure 6: Doctor facilitation and patient activation means at key time points

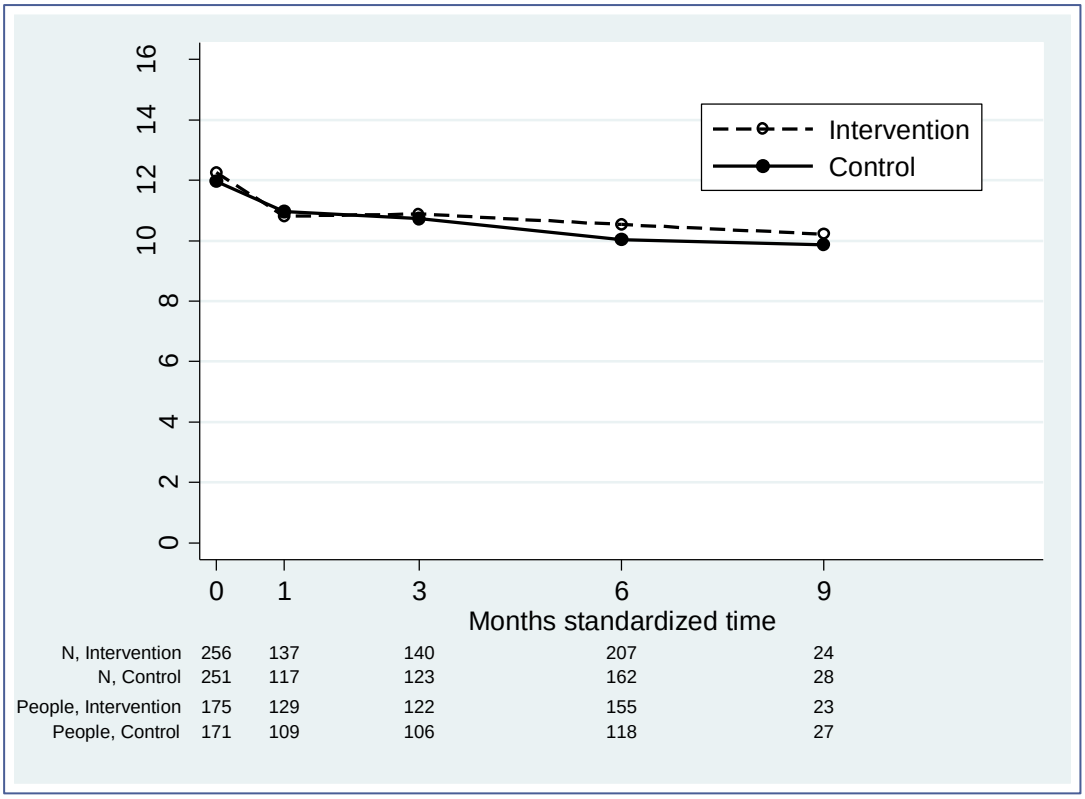

Figure 7: Doctor global positive affect means at key time points

Twelve Month Clinical Outcomes

A secondary objective of the study was to examine clinical outcomes of intervention and control patients to determine if the training had any effect on health outcomes. These outcomes (ART adherence, BMI, weight, CD4 count, and incidence of OIs and ART treatment interruptions) were not found to be statistically significantly different between the two treatment arms, either at 6 months or 12 (or more) months after study start (Table 6). Of note, however, this objective of the study was hampered by implementation of the study in a dynamic non-research environment; this affected the number of participants who were able to be followed for a full 12 months or longer and greatly reduced the sample size at the 12 month time point. Also, the majority of ART patients only visit the clinic every 3-6 months after one year of ART, limiting the possibility that study patients would be seen at the clinic at 12 months or later. Finally, data abstracted from patient charts at the 4 ART clinics proved to be unreliable. Some clinics do not conduct pill counts, for example, and adherence data (when available) had to be indirectly measured by whether pills were picked up or not or by the mean number of days between pill pickups (only in the case of Katutura Health Centre, where national data were available). The ART clinics also do not routinely run CD4 counts, especially after the first 2-3 months that a patient is on ART and documentation of OIs and ART interruptions is also unreliable (at 6 months only 42 CD4 counts were available). Clinics do not collect patient height so if study staff did not collect patient height it was impossible to calculate BMI. It is possible, though, given the positive effect of the training at 6 months that clinical outcomes could have been impacted by the intervention and a larger sample size and more reliable measures may have been able to detect this impact.

Table 6: Clinical outcomes at 6 and 12 months by study arm

Outcome measure	6 months			12 months		
	Group 1 (intervention)	Group 2 (control)	P-value	Group 1 (intervention)	Group 2 (control)	P-value
Adherence – pill count (Mean and SD*)	86.3 (33.5) N=322	90.2 (30.7) N=385	0.10	78.1 (44.4) N=9	75.3 (57.2) N=7	0.91
Adherence – pills picked up on required date (y/n)	253 (89%) N=284	253 (92%) N=274	0.40	52 (95%) N=55	40 (91%) N=44	0.48
Adherence – mean number of days between pill pickups and SD	43.6 (37.6) N=606	42.1 (39.8) N=659	0.48	73.4 (55.6) N=64	86.9 (10.4) N=50	0.27
BMI	22.3 (3.6) N=271	22.1 (3.5) N=246	0.68	22.5 (3.1) N=54	22.2 (4.1) N=37	0.70
Weight (Mean and SD)	60.4 (11.5) N=412	60.3 (10.5) N=385	0.90	59.3 (10.0) N=60	60.1 (11.7) N=38	0.48
CD4 Count (Mean and SD)	400.9 (193.4) N=20	463.8 (197.9) N=22	0.30	447 (247) N=6	521 (214) N=10	0.54
Opportunistic Infections	18 (3%) N=520	22 (4%) N=537	0.56	1 (1%) N=96	0 (0%) N=69	0.39
ART Treatment Interruptions	6 (1%) N=501	3 (.6%) N=521	0.89	0 (0%)	0 (0%)	---

*SD=Standard Deviation

DISCUSSION

This study has shown a positive impact of the patient education and empowerment curriculum intervention on patient-provider interactions. This is strongly supported by the statistically significant findings in 5 of the 13 RIAS and global affect outcomes measured at the 6 month time point and in the positive direction of all 13 outcome effect sizes in support of the intervention group (Table 6). The fact that the intervention group was positively impacted by the trainings is further supported by qualitative findings from training evaluations. As part of process monitoring, patients interviewed either after a training, or during a smaller number of in-depth interviews, consistently reported very positive feedback about the training and its relevance and applicability to their ART care at the clinic. These patients felt positive about not only the empowerment and question-asking components of the trainings but also about the basic education and information about ART, adherence, side effects and HIV biology – education that many felt was not available in any depth from the ART clinics. This combination of education and empowerment components in the curriculum was an important part of the training's success. Patients also enjoyed the camaraderie and support proffered by the other trainees and the trainer him/herself.

The training intervention also clearly impacted the providers themselves; doctors in the study gathered more information from trained patients, facilitated and activated patients and even showed more positive emotional affect during consultations. As an example of the types of interactions that combine as 'facilitation and activation of patients' these are times during a medical consultation when a doctor asks for a patients' opinion, asks for permission (to examine a patient, for example), asks for reassurance, or paraphrases and checks for understanding from the patient. Although the study indicated a boost in these types of interactions for the patients and doctors, it is disheartening that during ART follow up these positive interactions wane over time (Figures 3-7). This may reflect the energy and effort that providers put into consultations with early ART patients that is not sustained

In addition to utterance by utterance categorization, coders were asked to rate the affect or emotional context of the dialogue. These ratings were based on overall affective impressions of the speakers on such dimensions as dominance, assertiveness, friendliness, warmth, attentiveness and respectfulness. It is not clear why so few global affect categories had statistically significantly different effect sizes, as many of the RIAS categories did. It may be that coders were unfamiliar with either the format of the global affect scales or the definitions of the dimensions themselves (e.g., empathy or assertiveness) or these scales are too culturally-specific to Western health care systems and would need to be adapted more for use in Namibia or elsewhere. For RIAS coding, on the other hand, culturally-specific utterances during a consultation were discussed within the team and categorized according to a consensus of the study team.

As indicated earlier, study implementation challenges and the use of abstracted patient chart data hampered the study teams' ability to determine the training intervention impact on clinical outcomes. The reliability of abstracted data should be considered in future evaluation studies in Namibia.

In conclusion, ART is a lifelong therapy whose effectiveness depends on adherence to care and treatment. Patients need to feel that their role in care and treatment matters and this is partly dependent on the quality of their relationship with their provider. Given the immensity of HIV treatment campaigns in sub-Saharan Africa and elsewhere, more studies are needed to explore how patient-provider communication influences HIV care and treatment. In Namibia ART clinics should consider the positive impact on patient care that is possible from more targeted and in-depth patient education and empowerment.

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