



Evaluation of Pill Counts Adherence with Self-Reported Adherence in Assessing Antiretroviral Therapy Behavior of Women living with HIV at a Faith-based Clinic in Malawi

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Abstract

Background: Antiretroviral treatment is imperative for increasing survival among HIV positive individuals. Treatment success is assured by strict adherence to antiretroviral therapy (ART) resulting in improved quality and quantity of life.

Aim: To compare visual analogue scale (VAS) (self-report) adherence with pill counts adherence reports of individuals receiving HIV treatment in a rural faith-based clinic while evaluating the relationships between those two adherence measures with medication side effects, food insecurity, demographic characteristics, and social-psychological constructs.

Methods: This is a non-experimental cross-sectional study of a convenience sample of 200 reproductive age HIV positive women on ART at a faith-based clinic in Makwasa, Thyolo District, Malawi. Pill counts, VAS adherence, and other constructs measurements were taken from November to December 2013. Bivariate analysis was used to test the association between the two adherence outcomes and background factors and univariate logistic regression (ULR) models were used to explore the association of each variable to the two adherence outcomes; and multivariate logistic regression (MLR) was used to examine the association between outcome variables and adherence determinants.

Results: Mean pill count adherence was 79.00 ± 29.66 compared to 96.55 ± 14.21 for VAS adherence. Household food insecurity (OR=1.40; $P=0.01$), individual food insecurity (OR=1.54; $P=0.00$), and self-efficacy (OR=2.93; $P=0.00$) were significantly associated with pill count in the ULR. Household (OR=0.44; $P=0.00$) and individual food insecurity (OR=0.38; $P=0.003$), self-efficacy (OR=0.35; $P=0.04$), subjective norms (OR=0.24; $P=0.02$), and attitude (OR=0.34; $P=0.04$) were associated with VAS adherence in the ULR. In the multivariate, self-efficacy (adjusted) was associated with pill count, while attitude (adjusted) was associated with VAS adherence.

Conclusions: The study showed that a gap existed between VAS adherence and pill counts adherence indicating the participants verbally overestimated their adherence. Additionally, intervention focusing on food supplements would be useful for improving poor adherence associated with food insecurity.

Keywords: Faith-based HIV clinic; Antiretroviral therapy (art); Food insecurity; Reproductive age women; Thyolo makwasa malamulo malawi; Pill counts adherence; Visual analogue scale (vas)

Introduction

Antiretroviral therapy (ART) is offered at public/government, private and faith-based hospitals and health centers [1] throughout Malawi. It is provided free of charge [2], with the Ministry of Health in control of the treatment programs. As of 2013, there were 689 health facilities offering antiretroviral therapy to patients [3].

At the time of study in 2013, the World Health Organization (WHO) recommended that an individual starts ART treatment once his/her CD4 count was ≤ 350 cells/mm³ [4]. Malawi implemented the 2013 WHO's guidelines on HIV treatment by adopting the more liberal CD4 count threshold for initiating ART (350 cells/cu.mm) and switching first-line ART from stavudine (d4T) to tenofovir (TDF)-containing regimens [5]. The Malawi government has tried to meet WHO's recommendations by getting more patients into treatment.

There has been a long-standing debate on a standard threshold for adherence [6,7] because HIV begins to replicate at different drug plasma concentrations particular to each drug. According to the Centers for Disease Control and Prevention [8] (CDC), "medication adherence is

the patient's conformance with the provider's recommendation with respect to timing, dosage, and frequency of medication-taking during the prescribed length of time".

A systematic review conducted by Mills et al. [9], showed that adults' non-adherence rates ranged from 33% to 88% depending on adherence definitions. In Malawi, adherence to ART has been a challenge because following adherence requirements are difficult for patients so providers have to carefully monitor side effects of the medication [10]. Having free access to ART does not mean all who need it receive it. Factors

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such as the cost of transportation to the clinic for treatment, labor shortages, inadequate clinic and pharmacy space, shortages of drugs, discrimination by healthcare providers, and regular access to adequate food and water to be taken with the medication have been found to prevent individuals from taking ARTs consistently or at all, especially in rural areas, which has contributed to poor retention in treatment [10-15].

To understand ART adherence behavior of women receiving ART from a faith-based ART clinic, we assessed attitude toward ART, subjective norm, perceived behavioral control (self-efficacy), intention, food insecurity, medication side effects, and ART pill counts and VAS reports. The theory of planned behavior was utilized as the framework for this study [16] because it is the most cited model in HIV and AIDS research, and researchers have frequently used it to predict HIV and AIDS health behavior [17-19]. According to the theory, an individual's attitude toward treatment adherence includes evaluative opinions of the individual regarding the positive and negative outcomes of a behavior (ART adherence) [20]. An individual's positive attitude toward a behavior is associated with its practice as opposed to a negative attitude [21]. Subjective norms are an individual's evaluation of family and friends' expectations of a specific behavior [22]. Subjective norms are based on the idea that social pressure/support encourages individuals to act in what they consider a socially desirable manner and that people are then driven to conform to these social expectations [16-23]. Perceived behavioral control also known as self-efficacy refers to an individual's belief/confidence that he or she can engage in the behavior, while considering internal and external control factors. The constructs 'food insecurity' and 'medication side effects' were included in the model because we were interested in identifying factors that prevent Malawian women living with HIV from adhering to ART. The rationale for food insecurity was that individuals who experience severe side effects due to lack of food are more likely to believe that lack of food is a barrier to their ART adherence [11,12]. In addition, researchers show that food insecurity and medication side effects, although independent of each other, are strongly associated with patients' adherence behavior [24,25].

The aim of this study was to compare visual analogue scale (VAS) (self-report) adherence with pill counts adherence reports of individuals receiving HIV treatment in a rural faith-based clinic while assessing the relationships between those two adherence measures with medication side effects, food insecurity, demographic characteristics, and social-psychological constructs.

Materials and Methods

Study setting

The study was conducted at an approved HIV treatment (ART clinic) center at the Malamulo Hospital (located in the southwest zone, with less ART access). The prevalence of HIV among women age 15-49 years old in the southern region of Malawi is 17.6% (out of 14.5% in the region), which is higher than those in the Northern (8.2%) and Central (9%) regions [26]. The faith-based hospital is located about 65 kilometers southeast of Blantyre City in southern Malawi in Thyolo district [27]. Thyolo district has an HIV prevalence of 21% [28,29]. The 200 bed hospital is located in a rural area and serves about 129,000 people [30]. The hospital has fifteen mobile sites and three non-mobile clinics which operate on a daily basis [27]. The hospital clinic provides the following services: (a) HIV testing and counseling; (b) ART services; (c) prevention of mother to child transmission (PMTCT); (d) in-patient nutrition provision; (e) infection prevention and control; (f) management of sexually transmitted infections (STI); (g) family planning; and (h) static and outreach mother and child health (MCH)

services. ART regimens are based on the recommendation of the Malawi National AIDS Commission [15].

Participants

A convenience sample of two hundred women between ages 18-49 years old participated in guided survey interviews. In order to participate in the study, women had to be: a) on treatment at the Malamulo ART Clinic, b) on ART for at least 6 months, and c) able to understand spoken English or Chichewa to take part in the study. We were interested in studying adherence behavior of reproductive age women because of the high rate of HIV among this population in Malawi [31]. Women in Malawi account for the majority (51%) of those living with HIV/AIDS [32]. Women who met all of the conditions and were willing to participate but did not meet the age or length on ART medication criteria were excluded. Those receiving treatment from different health facilities other than the site of interest, or who had just started treatment were also excluded. This study was a follow-up to another study by McKinney et al. on patients and healthcare providers' perceptions of factors that influence adherence at two ART clinics in Malawi and patients' intentions to adhere to ART [11,12]. Participants were read the informed consent form and asked to give a verbal consent. Each participant was given a copy of the informed consent for record keeping. A demographic face-to-face interview questionnaire was used to document participants' age, income, education level, marital status, parity, religion, and language (Chichewa or other).

Design and procedure

This study used a non-experimental cross-sectional design to investigate the association of food insecurity, attitudes toward ART, subjective norm/social pressure, self-efficacy, intention, and side effects of ART adherence of HIV positive women with adherence to ART. Data collection took place in December 2013. Participants were recruited through multiple approaches including direct solicitations and flyers. Potential subjects were informed of the study while leaving the treatment center. Participants who consented to be in the study were directed to one of the four specially trained research assistants. Verbal consent was given by each participant before an interview guided survey was administered either in the local language (Chichewa or English). Institutional Review Boards approval was obtained from Loma Linda University and the University of Malawi College of Medicine Research and Ethics Committee (CoMREC). The Chief Medical Officer for the hospital also approved the study.

Measures: The outcome variables were pill count (primary outcome) and VAS (secondary outcome) adherence to ART treatment. Pill count like other pharmacy-based adherence measure (PAMs) is more reliable for monitoring adherence because of its objective approach. PAMs are considered to be superior to self-reported measures [31]. The predictor variables were the TPB constructs (attitude toward adherence, subjective norms, self-efficacy (perceived behavior control), and intention to adhere), perceived side effects, and food insecurity. Possible confounding variables were age (18-28, 29-39, 40-50, and other), income level (<162,998 MWK, >=162,998 MWK), level of education (No formal education, did not complete primary school, primary school or higher), marital status (married, never married, widowed, divorced, separated), parity (no children, at least one child), language (Chichewa, English, or other), pregnant (yes or no), and religion (Seventh-day Adventist, Catholic, Muslim, Pentecostal, Traditional religion, other Christians, and other).

Adherence: Two methods were used to assess adherence to antiretroviral therapy: 1) the VAS self-report one-month recall as used by Saal [31] 2) and pill count. Pill count was calculated as the number

of pills taken by subtracting the number of pills left in the bottle during a patient scheduled pharmacy refill appointment from the number of pills given. The number of pills participants were expected to have taken was calculated by multiplying the daily dose by the number of days since the date of pills dispensed. The number of pills taken was then divided by the total number of pills at the beginning, which was then multiplied by 100 to get the percent of pill count adherence [33]. We defined successful adherence on pill count as 90-100% of pills taken during follow-up appointment. The one-month self-report consisted of a 10 cm long VAS [34], where subjects were asked to indicate on the line approximately the percentage of the prescribed medication they took in the last month. The VAS ranged from 0-100, with 0 indicating no pills were taken, 50 indicating half of the pills were taken, and 100 indicating all of the pills were taken. Self-reported adherence to antiretroviral therapy was based on the estimated percentage of medications taken during the last month, with less than 95% of medications taken considered to be poor adherence. Pill count was used to compare participants' self-report of their adherence from their last visit.

Food insecurity: Food insecurity was assessed using the household and individual/adult level modified version of the Radimer [35] food insecurity scale used by Kendall [36]. The individual/adult level subscale consists of four questions with a Cronbach's alpha of 0.86 [37]. The household level subscale consists of five questions with a Cronbach's alpha of 0.84 [37]. The responses for both scales were rated on a 5-point scale as follows: access = *disagree a lot* to 5=*agree a lot*, that respondents and their household had access to food to assist respondents' adherence to ART.

Additional constructs: Attitude, which is participants' attitude toward ART was measured using four-item questions with a 5-point Likert scale. Subjective norm was measured as participants' perceptions regarding social pressure from people whose opinions were important as they related to the respondents' taking ART; it was assessed with the use of a four-item 5-point Likert scale. Self-efficacy/perceived behavioral control was defined as perceived ease of adhering to ART; it was assessed using five-item 5-point Likert scale questions. Intention, which was defined as planning to take ART as prescribed was measured using four item Likert-scale type questions. Perceived side effect which was defined as participants' perception of side effects when taking medication was measured using a five-item Treatment Satisfaction Questionnaire for Medication (TSQM) scale [38].

Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) (IBM Corp, New York) version 23 for windows. We explored the internal consistencies of the scores produced for each of the variables (intention, attitude, subjective norm, self-efficacy, food insecurity, and side effects) using Cronbach's Alpha. We calculated the means and standard deviations for pill count and VAS adherence along with the other variables using descriptive statistics. The association between the two adherence outcomes and background factors was assessed in a bivariate analysis. Univariate logistic regression (ULR) models were used to explore the association of each variable to the two adherence outcomes. Variables with a $p \leq 0.05$ from the ULR were included in the multivariate logistic regression (MLR) model. We built two models, one for each outcome variable. Statistical significance was set at the $p \leq 0.05$ level for the final models. Odds ratios (ORs) were adjusted for possible confounders (age, education, income, pregnancy, parity, marital status, language, and religion).

Power analysis

For the investigation of TPB constructs and other predictive

constructs in the model, Ajzen [39] suggests using multiple linear regression analysis as the most appropriate method for predicting each adherence intention on behavior. Using G*Power 3.1.3 program, the following were used for an effective analysis: a medium effect size, power of 0.80, and an alpha of 0.05 in order to obtain sample size estimates. In addition to the four theoretical constructs (intention, attitudes, subjective norms, and self-efficacy), the analysis included other variables such as food insecurity and medication side effects while controlling for age, marital status, income, education, pregnancy, religion, parity, and language; therefore, a total of 14 predictor variables were included in the regression models to obtain a sample size of 135. In order to obtain adequate power, the sample size was increased to 200.

Results

Descriptive and demographic data

Thirty-four (17%) of the 200 participants forgot to bring their ART bottles to their study visit, (but did take part in the self-report interviews). These participants were excluded from pill counts analysis. Characteristics of participants are summarized in Table 1. Most (51%) participants were between the ages of 29-39 years, married (67%), had less than primary school education (82.5%), had at least one child (94.4%), made less than \$400 (162,998 Malawian kwacha) annually (99.6%), and spoke Chichewa as their primary language (58.3%). The most common religious affiliation was Seventh-day Adventist Christian (27.1%), which is not surprising, since Seventh-day Adventist Health System operates the clinic where the study took place.

The mean for VAS adherence was 96.55%, indicating participants reported high adherence. Meanwhile, the mean for pill count adherence was 79.0%, indicating poor adherence. The Cronbach's Alpha for internal consistency for subjective norm was 0.95 followed by 0.93 for side effects, 0.90 for intention, 0.86 for household food insecurity, 0.84 for individual food insecurity, 0.75 for attitude, and 0.72 for self-efficacy.

Based on the mean (table not included), it appears participants had a high self-efficacy/confident that they could regularly take their

| Variables | N | % | Variables | N | % |
|--------------------------------------|-----|-------|-----------------------|-----|-------|
| Parity | | | Language | | |
| No children | 11 | 5.6% | Chichewa | 116 | 58.3% |
| At least one child | 187 | 94.4% | Other | 83 | 41.7% |
| Age range | | | Religion | | |
| 18-28 | 22 | 11.0% | Seventh-day Adventist | 54 | 27.0% |
| 29-39 | 102 | 51.0% | Catholic | 31 | 15.5% |
| 40-50 | 76 | 38.0% | Muslim | 4 | 2.0% |
| Pregnant | | | Pentecostal | 38 | 19.0% |
| Yes | 3 | 1.5% | Traditional religion | 15 | 7.5% |
| No | 197 | 98.5% | Other Christians | 43 | 21.6% |
| Education | | | Other | 14 | 7.0% |
| Less than primary school | 165 | 82.5% | Marital status | | |
| Primary school or more | 35 | 17.5% | Married | 134 | 67.0% |
| Income level | | | Never Married | 17 | 8.5% |
| Less than Malawian Kwacha162, 998 | 199 | 99.6% | Other | 49 | 24.5% |
| Greater than Malawian Kwacha162, 998 | 1 | 0.5% | | | |

Table 1: Socio-demographic characteristics of sample of participants at ART clinic.

medications on time. They also had a high intention to adhere to ART, positive attitude toward ART, high social pressures/supports to take their ART, experienced severe side effects to ART, and experience average lack of access to food on individual and household levels.

Adherence outcomes

Results of the bivariate analysis are shown in Table 2. When stratifying descriptive analysis by pill count adherence above ($\geq 90\%$) and below ($< 90\%$) the threshold for “adequate” adherence, the following variables: age (29-39), being married, having less than primary education, being non-Adventist and Catholic, having at least one child, and not being pregnant were associated with non-adherence. In the ULR, pill count adherence was significantly associated with individual (OR 1.54, 95% CI=1.16-2.05) and household (OR 1.40, 95% CI=1.08-1.81) food insecurity and self-efficacy (OR 2.94, 95% CI=1.43-6.04) (Table 3). In the final MLR model with confounders (age, education level, income, language, parity, pregnancy, religion) adjusted for, self-efficacy (OR 0.36, 95% CI=0.15-0.89) remained significantly associated with pill count adherence, adjusting for socio-demographic factors (Table 4). In terms of VAS adherence, age (29-39) and not speaking Chichewa were associated with non-adherence in the bivariate analysis. In the ULR, VAS adherence was significantly associated with individual (OR 0.38, 95% CI=0.21-0.72) and household (OR 0.44, 95% CI=0.26-0.76) food insecurity, self-efficacy (OR 0.35, 95% CI=0.13-0.97), subjective norms (OR 0.24, 95% CI=0.07-0.79), and attitudes toward ART (OR 0.34, 95% CI=0.12-0.94). In the final MLR model, attitude toward ART remained significantly associated with VAS adherence (OR 0.18, 95% CI=0.04-0.82), adjusting for socio-demographic factors (age, education level, income, language, parity, pregnancy, religion).

When not adjusting for potential confounders (age, education level, income, language, parity, pregnancy, religion), self-efficacy (OR 0.41, 95% CI=0.18-3.91) remained statistically associated with pill count adherence while attitude (OR 0.26, 95% CI=0.08-0.86) remained statistically associated with VAS adherence. Similar to the final MLR models where demographic factors were adjusted for, individual and household levels food insecurity was no longer associated with pill count adherence. The same is accurate for VAS adherence. Individual and household levels food insecurity, subjective norms, and self-efficacy were no longer associated with VAS adherence in the final MLR models for both adjusted and non-adjusted confounders.

Discussion and Conclusion

This non-experimental cross-sectional study compared pill count adherence with VAS adherence while assessing the relationships between those two adherence measures with attitude, self-efficacy, subjective norm, and intentions along with food insecurity and medication side effects among reproductive age Malawian women living with HIV and AIDS. Our study had much agreement with the literature.

| | P-value | OR | 95% C.I. | |
|----------------------------|---------|------|----------|------|
| Individual food insecurity | 0.003 | 1.54 | 1.16 | 2.05 |
| Household food insecurity | 0.011 | 1.40 | 1.08 | 1.81 |
| Self-efficacy | 0.003 | 2.94 | 1.43 | 6.04 |
| VAS Adherence | P-value | OR | 95% C.I. | |
| Household Food Insecurity | 0.003 | 0.44 | 0.26 | 0.76 |
| Individual Food Insecurity | 0.003 | 0.38 | 0.21 | 0.72 |
| Self-efficacy | 0.044 | 0.35 | 0.13 | 0.97 |
| Subjective Norms | 0.018 | 0.24 | 0.07 | 0.79 |
| Attitude | 0.037 | 0.34 | 0.12 | 0.94 |

Table 2: Univariate logistics regression of pill count and vas adherence measures.

While the average pill count adherence was 79%, which is below the threshold recommended by WHO, VAS adherence was 97% (Figure 1), which is a little above the recommended 95% threshold for adherence. Other studies have shown similar findings for adherence in middle and low-income countries. In a systematic review of adherence in low- and middle-income countries by Vreeman et al. [40], they indicated adherence estimates to be between 49% to 100%, with more than half of the articles reporting adherence greater than 75%. Meanwhile, in an earlier meta-analysis by Mills et al. [41], adherence threshold in Sub-Saharan Africa was reported at greater than 80%, which is consistent with Vreeman’s report. Pill count adherence inaccurately measured adherence when compared to self-report recall (VAS). This could be due to the missing data in pill count, which were not included in the analysis.

Household and individual food insecurity were associated with pill count non-adherence and having confidence about taking ART was also associated with pill count adherence. In the VAS adherence, we found that reproductive age women who took their medication regularly were more likely to have a positive attitude toward ART and high social support. Non-adherence was significantly associated with household and individual food insecurity. Self-efficacy was associated with VAS adherence and pill count [42] adherence. This is in agreement with Atkinson et al. [6] who reported factors that strongly influence patients’ medication adherence to include patients’ optimism, treatment self-efficacy, and understanding of HIV treatment benefits. Negative perception about exerting control over behavior could act as barrier to adherence [43]. A strong association was found between adherence and self-efficacy among non-adherent samples in Pretoria, South Africa [44].

Participants’ attitude toward the medication was also associated with VAS adherence. Participants’ attitude can have a major impact on their adherence behavior, depending on its direction, i.e., positive or negative. This finding is in agreement with other studies which have found patient-related barriers to adherence to include patients’ belief, attitude and behavior towards medication, which contributed to suboptimal [45] or non-adherence [43]. Since attitudes can be modifiable, it is possible for the development of interventions that focus on increasing individual’s positive attitude toward ART.

Food insecurity played a major impact on adherence directly. It was found to be directly associated with VAS adherence and pill counts. This is in agreement with numerous studies and a meta-analysis [46-48] which have reported an association between food insecurity and ART adherence. Food insecurity has been found to be associated with poor antiretroviral adherence among people living with HIV (PLHIV) [49]. Other studies have established strong relationship between food insecurity and non-adherence [48]. Using unannounced pill counts and pharmacy refill, Kalichman et al. [50] and Weiser et al. [49] found an association between food insecurity and non-adherence among urban poor PLHIV in the United States. Lyimo et al. [51], found an association between non-adherence and unavailability of food. These studies along with ours indicate that interventions to increase adherence for this population should focus on food access. An estimated 97% of rural women in Malawi engage in subsistence farming to meet their food needs and their diets are not balanced [52]. Malawian women produce 70% of household food and perform about 50-70% of all agricultural tasks [53]. Maize, the staple food crop in Malawi, is grown by 97% of farming households [54]. Maize contributes 60% to total calorie consumption in Malawi [54]. A high burden of undernutrition is present in Malawi, with stunting among children under 5 staggering higher than other African countries (Ethiopia, Guinea Bissau, Eritrea, Tanzania, Zambia, and Liberia) with the same GNI per capita [55].

| | OR | p-value | 95% C.I. | |
|-----------------------------------|------------|-----------|-----------|-----------|
| Age (40-50) | ref | ref | ref | ref |
| Age (18-28) | 2.16 | 0.22 | 0.64 | 7.33 |
| Age (29-39) | 0.98 | 0.97 | 0.44 | 2.21 |
| Education (Beyond primary school) | ref | ref | ref | ref |
| Education (Less than primary) | 0.93 | 0.87 | 0.37 | 2.31 |
| Income (Above K162,998) | ref | ref | ref | ref |
| Income (Less than K162,998) | 2.50 | 0.32 | 0.60 | 5.01 |
| Language (Other) | ref | ref | ref | ref |
| Language (Chichewa) | 1.17 | 0.69 | 0.53 | 2.59 |
| Marital status (Other) | ref | ref | ref | ref |
| Marital status (Married) | 0.70 | 0.40 | 0.30 | 1.62 |
| Marital status (Never married) | 1.00 | 0.99 | 0.23 | 4.42 |
| Pregnant (Yes) | ref | ref | ref | ref |
| Pregnant (No) | 0.67 | 0.80 | 0.13 | 5.59 |
| Parity (At least one child) | ref | ref | ref | ref |
| Parity (No children) | 1.11 | 0.88 | 0.26 | 4.76 |
| Religion (Other religion) | ref | ref | ref | ref |
| Religion (Seventh-day Adventist) | 0.90 | 0.78 | 0.38 | 2.07 |
| Religion (Catholics) | 1.26 | 0.64 | 0.48 | 3.32 |
| Individual Food Insecurity | 1.94* 2.25 | 0.08* | 0.91* | 4.16* |
| | | 0.72 | 0.93 | 5.47 |
| Household Food Insecurity | 0.67*0.68 | 0.27* | 0.33* | 1.37* |
| | | 0.22 | 0.25 | 1.37 |
| Self-efficacy | 0.41*0.36 | 0.04* | 0.18*0.15 | 3.91*0.89 |
| | | 0.03 | | |
| VAS Adherence | OR | P-value | 95% | C.I. |
| Age (40-50) | ref | ref | ref | ref |
| Age (18-28) | 2.03 | 0.98 | 0.50 | 3.06 |
| Age (29-39) | 0.19 | 0.05 | 0.04 | 1.03 |
| Education (Beyond primary school) | ref | ref | ref | ref |
| Education (Less than primary) | 0.50 | 0.52 | 0.06 | 4.10 |
| Income (Above K162,998) | ref | ref | ref | ref |
| Income (Less than K162,998) | 0.23 | 0.32 | 0.03 | 1.01 |
| Language (Other) | ref | ref | ref | ref |
| Language (Chichewa) | 0.35 | 0.18 | 0.08 | 1.64 |
| Marital status (Other) | ref | ref | ref | ref |
| Marital status (Married) | 1.75 | 0.54 | 0.29 | 10.53 |
| Marital status (Never married) | 0.93 | 0.95 | 0.08 | 11.34 |
| Pregnant (Yes) | ref | ref | ref | ref |
| Pregnant (No) | 4.22 | 0.98 | 0.06 | 3.96 |
| Parity (At least one child) | ref | ref | ref | ref |
| Parity (No children) | 3.24 | 0.98 | 1.91 | 1.97 |
| Religion (Other religion) | ref | ref | ref | ref |
| Religion (Seventh-day Adventist) | 1.47 | 0.66 | 0.27 | 8.03 |
| Religion (Catholics) | 0.16 | 0.04 | 0.03 | 0.98 |
| Individual Food Insecurity | 1.01*0.74 | 0.99*0.78 | 0.25*0.10 | 4.07*5.52 |
| Household Food Insecurity | 0.63*0.75 | 0.48*0.77 | 0.18*0.11 | 2.27*5.28 |
| Subjective Norm | 0.16*0.12 | 0.11*0.14 | 0.02*0.01 | 1.55*1.92 |
| Attitude | 0.26*0.18 | 0.03*0.03 | 0.08*0.04 | 0.86*0.82 |
| Self-efficacy | 0.87*0.54 | 0.89*0.65 | 0.13*0.04 | 6.00*7.88 |

*unadjusted values

Table 3: Multivariate logistics regression of pill count and vas adherence.

According to the United Nations World Food Program (WFP), an estimated 60% of people in the rural regions of Malawi live below poverty level and do not meet minimal nutritional needs [56].

Although medication side effects were not directly associated with adherence, it had an indirect influence on ART adherence (table not shown). The relationship was mediated by food insecurity and attitudes

| | | Pill count adherence | | VAS adherence | |
|----------------|--------------------------|----------------------|---------------|---------------|---------------|
| | | Adherence | Non-adherence | Adherence | Non-adherence |
| | | n (%) | n (%) | n (%) | n (%) |
| Age | 18-28 | 10 (12.5) | 9 (10.5) | 22 (12.2) | 0 (0.0) |
| | 29-39 | 40 (50.0) | 45 (52.3) | 90 (49.7) | 12 (63.2) |
| | 40-50 | 30 (37.5) | 32 (37.2) | 69 (38.1) | 7 (36.8) |
| Education | Less than Primary school | 65 (81.3) | 68 (79.1) | 148 (81.8) | 17 (89.5) |
| | Primary school or more | 15 (18.8) | 18 (20.9) | 33 (18.2) | 2 (10.5) |
| Income | Less than K162,998 | 80 (100.0) | 85 (98.8) | 180 (99.4) | 19 (100.0) |
| | Greater than K162,008 | 0 (0.0) | 1 (1.2) | 1 (0.6) | 0 (0.0) |
| Language | Chichewa | 46 (57.5) | 44 (51.8) | 107 (59.4) | 9 (47.4) |
| | other | 34 (42.5) | 41 (48.2) | 73 (40.6) | 10 (52.6) |
| Marital status | Married | 52 (65.0) | 60 (69.8) | 123 (68.0) | 11 (57.9) |
| | Never married | 7 (8.8) | 6 (7.0) | 14 (7.7) | 3 (15.8) |
| | Other | 21 (26.3) | 20 (23.3) | 44 (24.3) | 5 (26.3) |
| Parity | No children | 5 (6.3) | 6 (7.1) | 11 (6.1) | 0 (0.0) |
| | At least one child | 74 (93.7) | 79 (92.9) | 168 (93.9) | 19 (100.0) |
| Pregnant | Yes | 2 (2.5) | 1 (1.2) | 3 (1.7) | 0 (0.0) |
| | No | 78 (97.5) | 85 (98.8) | 178 (98.3) | 19 (100.0) |
| Religion | Seventh-day Adventist | 22 (27.5) | 25 (29.1) | 48 (26.5) | 6 (31.6) |
| | Catholic | 14 (17.5) | 12 (14.0) | 26 (14.4) | 5 (26.3) |
| | Other religions | 44 (55.0) | 49 (57.0) | 107 (59.1) | 8 (42.1) |

Table 4: Bivariate analysis of background variables with pill count (> or <90%) and vas (> or <95%) adherence.

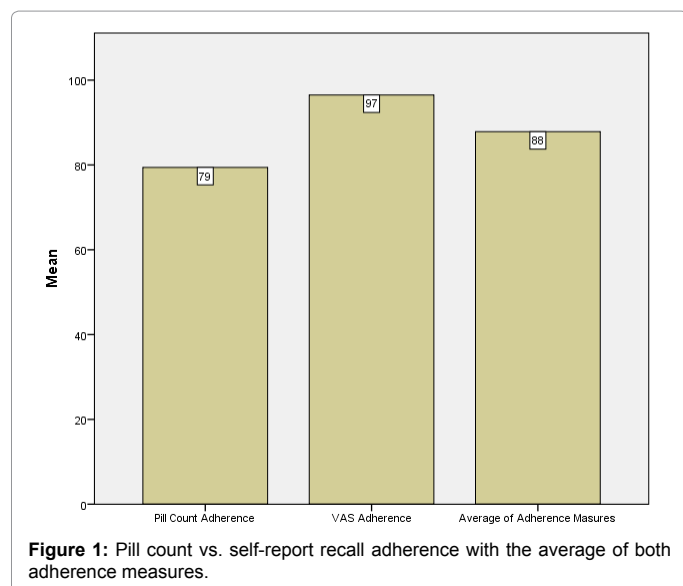


Figure 1: Pill count vs. self-report recall adherence with the average of both adherence measures.

toward ART. Atkinson et al. agree that medication side effects were among the strongest correlates of medication non-adherence [6]; it was also found to be associated with missed doses in Wasti et al. study [43]. Other studies reported treatment characteristics that contributed to non-adherence to include the frequency and severity of side effects and dietary requirements [6,7,57-59].

Pill counts adherence data, which was used as a validation against the women's self-report of adherence, was only associated with self-efficacy and individual and household food insecurity, while VAS adherence was associated with attitudes toward ART, subjective norms, self-efficacy, and household and individual food insecurity, with indirect association with medication side effects. The self-reported data showed

the women to have high adherence above the 'threshold' for adherence, while pill count, an objective measure of adherence, showed the women to be non-adherent. This implies that the women may have verbally overestimated their adherence, indicating a gap between past VAS adherences with pill counts adherence. If they had good self-efficacy, they took their medications well based on the pill counts adherence reports. If they had a poor attitude about ART, then they self-reported poor adherence. When the women had no access to food, they self-reported poor adherence, this is validated by the pill counts adherence. Living in a resource-limited environment with possible food insecurity issue can create a challenge in terms of following food instructions for taking ART. Policymakers who are interested in improving the quality of life for people living with HIV and AIDS in resource-limited areas should consider allocating funds to create programs/interventions focusing on food supplements, which could improve poor adherence associated with food insecurity.

Some of the possible limitations for this study include recall and social desirability bias due to the self-report nature of some of the data. With the use of pharmacy-based adherence measure, this limitation was addressed. The amount of missing data for pill count adherence is a possible limitation to this study. The lack of applicability of social cognitive models of health behaviors in resource-limited settings [11,60] could be perceived as a limitation as well. The theory of planned behavior may not be the most practical theory to use among rural non-literate population because of lack of translation of Likert scale in participants local cultures or languages [11]. Our study includes only women ages 18-49 years old with low social economic status receiving care at a rural faith-based ART clinics in southern Malawi, which is a strength for the study because it is the first of its kind to be conducted at this area with its unique cultural and societal characteristics. These results may be generalizable to similar populations within Malawi. Future research should assess the same constructs with men the same age bracket as samples, to assess if the results will be comparable with this study's population.

Competing Interest

The authors declare that there is no conflict of interests regarding the publication of this article.

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