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Title:
Female Adherence Self-Efficacy before and after Couple HIV Testing and Counseling within Malawi's Option B+ Program

Running Head:
Female Adherence Self-Efficacy in Option B+

Authors:

1. Austin Wesevich – University of North Carolina Project, Lilongwe, Malawi; Tidziwe Centre, Private Bag A-104, Lilongwe, Malawi; +1-919-620-5333; Austin.Wesevich@duke.edu
2. Mina C. Hosseinipour – University of North Carolina Project, Lilongwe, Malawi; Department of Medicine, University of North Carolina at Chapel Hill; Tidziwe Centre, Private Bag A-104, Lilongwe, Malawi; +265-175-5056; mina_hosseinipour@med.unc.edu
3. Carol E. Golin – Departments of Medicine and of Health Behavior, University of North Carolina at Chapel Hill; 135 Dauer Drive, Chapel Hill, NC 27559; +1-919-966-7939; carol_golin@med.unc.edu
4. Nuala McGrath – Departments of Primary Care and Population Sciences and of Social Statistics and Demography, University of Southampton; University Road, Southampton, SO17 1BJ, United Kingdom; +44(0)23 8059 5000; N.McGrath@soton.ac.uk
5. Mercy Tsidya – University of North Carolina Project, Lilongwe, Malawi; Tidziwe Centre, Private Bag A-104, Lilongwe, Malawi; mtsidya@unclilongwe.org
6. Limbikani Chimndozi – University of North Carolina Project, Lilongwe, Malawi; Tidziwe Centre, Private Bag A-104, Lilongwe, Malawi; lchimndozi@unclilongwe.org
7. Nivedita Bhushan – University of North Carolina Project, Lilongwe, Malawi; Department of Health Behavior, School of Public Health, University of North Carolina at Chapel Hill; 135 Dauer Drive, Chapel Hill, NC 27599; nbhushan@live.unc.edu
8. Irving Hoffman – University of North Carolina Project, Lilongwe, Malawi; Department of Medicine, University of North Carolina at Chapel Hill; Tidziwe Centre, Private Bag A-104, Lilongwe, Malawi; +265-175-5056; irving_hoffman@med.unc.edu
9. William C. Miller – Division of Epidemiology, The Ohio State University; 1841 Neil Ave., Columbus, OH 43220; +1-514-292-2516; miller.8332@osu.edu
10. Nora E. Rosenberg – University of North Carolina Project, Lilongwe, Malawi; Department of Health Behavior, University of North Carolina at Chapel Hill; Tidziwe Centre, Private Bag A-104, Lilongwe, Malawi; 919-602-8499; nora_rosenberg@unc.edu

Corresponding author:
Austin Wesevich
University of North Carolina Project
Austin.Wesevich@duke.edu

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Abstract

Adherence self-efficacy, belief in one's ability to adhere to taking medication daily, has been strongly associated with antiretroviral therapy (ART) adherence, an essential behavior for preventing mother-to-child transmission of HIV. Couple-based interventions have the potential to enhance adherence self-efficacy and ultimately adherence. We sought to assess the relationship between couple HIV testing and counseling (cHTC) and adherence self-efficacy using a 100-point culturally-adapted adherence self-efficacy scale (ASES). Secondarily, we explored the relationship between ASES and ART adherence. Ninety HIV-positive pregnant women at an antenatal clinic in Lilongwe, Malawi were enrolled in an observational cohort study. They were assessed with ASES immediately before and one month after receiving cHTC. Median ASES scores were 100 (IQR 95, 100) before and 100 (IQR 99, 100) after cHTC; there was a significant median difference (p=0.02) for participants before and after cHTC. This change in ASES scores was associated with the odds of self-reported ART adherence in the full population (OR 1.1, p=0.01), and there was a trend in the same direction for participants with imperfect baseline ASES scores (OR 1.1, p=0.2). In our population of HIV-positive pregnant women in Malawi's Option B+ program, adherence self-efficacy and ART adherence were both quite high, and those who had room to improve in self-efficacy may have benefited from cHTC, which in turn could impact ART adherence and ultimately mother-to-child transmission.

Keywords
adherence, self-efficacy, HIV, couples, Malawi, counseling

Introduction

In Malawi's Option B+ program, which provides lifelong antiretroviral therapy (ART) for HIV-positive pregnant and breastfeeding women (Schouten et al. 2011), half of early mother-to-child transmission events have occurred among mothers with known HIV status who are on ART (Tippett Barr et al. 2018). This observation suggests poor ART adherence and high viremia. ART adherence self-efficacy, belief in one's ART adherence ability, has consistently been linked to ART adherence (Been et al. 2016; Côté et al. 2016; Mao et al. 2018; McCoy et al. 2016; Voisin et al. 2017) and thus is an important target for intervention.

Couple HIV testing and counseling (cHTC) could improve ART adherence self-efficacy. Through cHTC, trained health workers provide HIV infection status results to both couple members together and, when applicable, support ART initiation, discuss adherence barriers and strategies, and promote partner support. Although studies examine the positive effects of couple-based interventions on self-efficacy in other health conditions (Chen, Liu, and You 2017; Arden-Close and McGrath 2017), there is no evidence assessing the impact of couple-based interventions on ART adherence self-efficacy (Johnson et al. 2012; Robbins et al. 2014; Ridgeway et al. 2018).

We aim to assess ART adherence self-efficacy changes after cHTC and the relationship between adherence self-efficacy and self-reported ART adherence.

Methods

Setting

The study was conducted from 2015-2016 at Bwaila District Hospital, a maternity hospital in Lilongwe, Malawi that provides antenatal care to 18,000 pregnant women annually and has offered Option B+ since 2011.

Study Design and Participants

This analysis was part of an observational cohort study of pregnant women and male partners. This analysis includes the 90 enrolled HIV-positive pregnant women but excludes HIV-negative women and all male partners. Couples presented for a baseline visit where cHTC was provided and a follow-up visit one month later. Further information can be found in earlier reports from the parent study (Rosenberg et al. 2017; Rosenberg et al. 2018).

Measures

We explored the change in the ART adherence self-efficacy score from baseline to one-month post-cHTC and the relationship between change in self-efficacy score and self-reported ART adherence one-month post-cHTC.

Self-efficacy was assessed at both visits using an adapted version of the HIV Treatment Adherence Self-Efficacy Scale (ASES) (Johnson et al., 2007). The original 12-item scale was validated in predominantly white, homosexual American men. HIV-positive

individuals were asked their confidence in carrying out treatment adherence behaviors under a variety of circumstances, with responses ranging from feeling unable to do it at all to feeling certain that one can do it. It has subsequently been used in a variety of settings with different ART regimens, including in Malawi (Cornelius et al. 2017; Sun et al. 2017; Been et al. 2016; McCoy et al. 2016; Adefolalu et al. 2014; Umar et al. 2019).

Formal adaptation procedures were followed (Terwee et al. 2007): translation, back-translation, and piloting (Sousa and Rojjanasrirat 2011). The pilot revealed two non-applicable items related to changed eating habits and T-cell counts. Thus, an abbreviated 10-item Chichewa version was used (Table 2). Item scores (0-10) were summed for a total score (0-100). For some analyses, overall scores were dichotomized (100 versus <100).

At follow-up, ART adherence was calculated based on self-reported 7-day recall. All participants were on a single daily tablet (tenofovir/lamivudine/efavirenz).

Several baseline covariates were collected: age, highest education level, flooring, number of days hungry over the past month, occupation, prior HIV testing and results, marital status, pregnancy duration, number of previous pregnancies, number of children, and partner HIV status.

Statistical Analysis

Covariates were compared between those with a baseline ASES scores of 100 and <100 using Fisher exact and Mann-Whitney U tests because of left-skewed ASES responses. Median overall ASES score difference and item-specific ASES score differences between those with baseline ASES of 100 and <100 were compared using Wilcoxon signed-rank tests.

Self-reported adherence was dichotomized into 7/7 days versus $\leq$6/7 days. Unadjusted and adjusted logistic regression models assessed whether changes in overall ASES scores predicted complete versus incomplete ART adherence. Adjustments were based on covariates significantly associated with the baseline ASES score (Table 1).

Analyses were performed using Stata 14.1 (College Station, Texas, USA).

Ethics

The study received approval from both the National Health Science Research Committee in Malawi and the University of North Carolina at Chapel Hill Institutional Review Board.

Results

The 90 HIV-positive women had a median age of 25 years (IQR 22,30) and almost all were married (99%), non-income-earning (84%), and newly diagnosed with HIV (93%) (Table 1). Only 24% of male partners were HIV-negative. The median time from HIV diagnosis to the baseline visit was 8 days (IQR 4,22).

ASES scores were collected at both visits for 76 (84%) participants. Ten (11%) were missing at baseline due to delayed implementation of the ASES scale, and four (4%) did not return for follow-up. These four had significantly lower baseline ASES scores than the 76 who returned (p=0.005). The median baseline ASES score was 100 (IQR 95,100), with 14% below 90, 22% from 90-99, and 63% at 100.

Comparing those who reported baseline ASES scores of 100 to <100, a statistical difference was only observed for male partner HIV status (p=0.03): women with HIV-negative partners were more likely to report perfect ASES scores (Table 1).

Overall median follow-up ASES score was 100 (IQR 99,100). Despite perfect median scores at both visits, the median difference was significant (median 0, IQR 0,4.5, p=0.02). Of the 48 participants (63%) with perfect baseline scores, only ten participants' ASES scores declined at follow-up (median -4.5, IQR -8,-3). Two items significantly decreased. Of the 28 participants (37%) with imperfect baseline ASES scores, two participants' ASES scores declined (median -18, IQR -22,-14), and 26 increased (median 8.5, IQR 4,17). Nine items significantly improved (Table 2).

ART adherence at follow-up ranged from 0/7 days to 7/7 days (median 7, IQR 7,7) but was strongly left-skewed: 84% 7/7 days, 8% 6/7 days, and 8% <6/7 days. In a multivariable model adjusted for male partner HIV status, change in overall ASES score was significantly associated with perfect ART adherence (OR 1.1, 95% CI 1.0, 1.3, p=0.01). When stratified by baseline ASES score (100 versus <100), change in overall ASES score trended positively with perfect ART adherence for participants with imperfect baseline ASES scores (OR 1.1, p=0.2).

Discussion

In a cohort of HIV-positive pregnant women, ASES scores statistically improved from immediately before cHTC to one month later. While many reported perfect baseline ASES scores, for those who did not, nine of the ten ASES items significantly increased after cHTC, reflecting a variety of ways self-efficacy could improve. Furthermore, change in ASES scores were positively associated with ART adherence.

The World Health Organization strongly endorses cHTC, which has been associated with changes in social support and consistent condom use (Rosenberg et al. 2017; Wall et al. 2017; Bhushan et al. 2018). This is the first study to show statistical improvement in self-efficacy scores following cHTC. Female self-efficacy could improve through cHTC via partner verbal persuasion, physiologic feedback of emotional support, and vicarious encouragement of seeing partners take ART successfully (Bandura 1977).

Our work builds on prior research in sub-Saharan Africa linking self-efficacy to ART adherence and viral suppression for pregnant women and adolescents (Brittain et al. 2018; Umar et al. 2019; Wagner et al. 2017) and in China demonstrating the mediating role of adherence self-efficacy in subsequent ART adherence ((Zhang et al. 2016; Chen et

al. 2018). Our findings suggest that partner dynamics could be an additional avenue by which to leverage the relationship between self-efficacy and ART adherence.

The rigorous ASES adaptation process was based on systematic methodology, but the resulting data were highly skewed. We observed limited variability in responses with 63% of participants reporting perfect scores at baseline, much higher than the average score when administered in South Africa (Adefolalu et al. 2014). This could be due to collecting baseline information roughly eight days after starting ART instead of when ART-naïve. Additionally, nearly all women reported perfect seven-day adherence at follow-up, which might be influenced by recall and social desirability biases (Berg and Arnsten 2006) and loss-to-follow-up of the likely least adherent participants given significantly lower baseline ASES scores. Scales are not routinely used in Malawi, and participants seemed to utilize the scale in a binary fashion (10 versus <10). The adapted, translated ASES scale should be tested for validity within this population, which might help delineate further adaptations needed.

Limitations included a small sample size, skewed responses to ASES and adherence measures, and lack of biologic data such as viral load. Additionally, because the analysis lacks a control group who did not receive cHTC, we are not able to determine whether the observed trends are the result of cHTC or simply from more elapsed time since diagnosis.

Nearly perfect ART adherence is essential for achieving viral suppression (Suleiman and Momo 2016; Kapiamba, Masango, and Mphuthi 2016). Our analyses suggest that cHTC may be a strategy for improving self-efficacy, which could play a role in improving ART adherence and viral suppression.

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Table 1. Comparison of baseline covariates and baseline ASES score

	ASES = 100 (n = 48)	**ASES < 100 (n = 28)**	**p-value**
	N (%)	*N (%)*	*Fisher exact*
Age Category			
18-19	2 (4%)	2 (7%)	
20-24	22 (46%)	10 (36%)	
25-29	12 (25%)	8 (29%)	
30-34	11 (23%)	6 (21%)	
35-39	1 (2%)	2 (7%)	0.7
Education Level			
No school	3 (6%)	4 (14%)	
Some primary	16 (33%)	9 (32%)	
Completed primary	8 (17%)	4 (14%)	
Some secondary	14 (29%)	7 (25%)	
Completed secondary	7 (15%)	4 (14%)	0.9
Flooring			
Sand/Dirt/Dung	8 (17%)	5 (18%)	
Cement/Tiles	36 (75%)	18 (64%)	
Other	4 (8%)	5 (18%)	0.4
Occupation			
Housewife/Unemployed	43 (90%)	25 (89%)	
Income-Earning	5 (10%)	3 (11%)	1.0
Income Support from husband? (1 Mo)			
None	4 (8%)	3 (11%)	
>$0	44 (92%)	25 (89%)	0.7
Prior HIV Testing			
Never tested	12 (25%)	8 (29%)	
Previously negative	34 (71%)	17 (61%)	
Previously positive	2 (4%)	3 (11%)	0.4
Male Partner's HIV status			
Male HIV-negative	16 (34%)	3 (11%)	
Male HIV-positive	31 (66%)	25 (89%)	0.03
	Median (IQR)	*Median (IQR)*	*Mann-Whitney U*
Days Elapsed from Diagnosis to Baseline Visit	9 (2,29)	8.5 (1,26)	0.8
Number of Marriages	1 (1,2)	2 (1,2)	0.3
Months Pregnant	5 (4,7)	5 (4,7)	0.7
Previous Pregnancies	1.5 (0,4)	3 (0,3)	0.5
Number of Children	1 (0,3)	1.5 (0,3)	0.6
Days Hungry (Past Month)	0 (0,2)	0 (0,3)	0.6

Table 2. Difference in median ASES scores before and after cHTC stratified by baseline ASES score

Variable	Median Difference (IQR) [Range] if ASES of 100 at baseline	p-value	Median Difference (IQR) [Range] if ASES < 100 at baseline	p-value
a) Stick to your treatment plan even when ***side effects*** begin to interfere with daily activities.	0 (0, 0) [-1, 0]	0.05	0 (0, 1) [0, 3]	< 0.01
b) Integrate your treatment into your ***daily routine***.	0 (0, 0) [-2, 0]	0.08	0 (0 ,0) [0, 2]	0.03
c) Integrate your treatment into your daily routine even if it means taking medication or doing things ***in front of other people*** who don't know you are HIV-infected.	0 (0, 0) [-10, 0]	0.08	1 (0, 5) [-7, 10]	< 0.01
d) Stick to your treatment schedule even when your ***daily routine is disrupted***.	0 (0, 0) [-10, 0]	< 0.01	1 (0, 2) [-5, 10]	< 0.01
e) Stick to your treatment schedule when you ***aren't feeling well***.	0 (0, 0) [-2, 0]	0.2	1 (0, 1.5) [-9, 10]	< 0.01
f) Continue with your treatment even if doing so interferes with your ***daily activities***.	0 (0, 0) [0, 0]	-	0 (0, 1) [-2, 10]	< 0.01
g) Continue with your treatment even when you are ***feeling discouraged*** about your health.	0 (0, 0) [0, 0]	-	0 (0, 0) [0, 10]	0.2
h) Continue with your treatment even when getting to your ***clinic appointment is a major hassle***.	0 (0, 0) [-10, 0]	0.01	1 (0 ,1) [-2, 10]	< 0.01
i) Continue with your treatment even when people close to you tell you that they ***don't think that it is doing any good***.	0 (0, 0) [0, 0]	-	0 (0, 1) [-2, 10]	0.02
j) Get something positive out of your participation in treatment, even if the medication you are taking ***does not improve your health***.	0 (0, 0) [-1, 0]	0.2	1.5 (1, 3.5) [-4, 10]	< 0.01
ASES Sum	0 (0, 0) [-22, 0]	< 0.01	8 (2.5, 17) [-22, 59]	< 0.01