AIDS and Behavior (2018) 22:1039–1052
https://doi.org/10.1007/s10461-017-2013-1

ORIGINAL PAPER

Improving AIDS Care After Trauma (ImpACT): Pilot Outcomes of a Coping intervention Among HIV-Infected Women with Sexual Trauma in South Africa

Kathleen J. Sikkema[1,2,3,4] · Marta I. Mulawa[1] · Corne Robertson[3] · Melissa H. Watt[1] · Nonceba Ciya[3] · Dan J. Stein[3] · Emily M. Cherenack[1,2] · Karmel W. Choi[1,2] · Matapelo Kombora[3] · John A. Joska[3]

Published online: 21 December 2017

Abstract
Improving AIDS Care after Trauma (ImpACT), a coping intervention for HIV-infected women with sexual abuse histories, was evaluated for feasibility and potential efficacy in a public clinic in Cape Town, South Africa. Sixty-four participants were enrolled prior to starting antiretroviral therapy (ART). After completing baseline assessments, participants were randomly assigned to standard of care (SoC: three adherence counseling sessions) or ImpACT (SoC plus four individual and three group sessions). Participants completed assessments at 3 months (after individual sessions) and 6 months post-baseline. In exploratory analysis of primary outcomes, ImpACT participants, compared to SoC, reported greater reductions in avoidance and arousal symptoms of PTSD and greater increases in ART adherence motivation at 3 months. Clinically significant decreases in overall PTSD symptoms were also demonstrated at 3 months. These effects continued as trends at the 6-month assessment, in addition to increases in social/spiritual coping. In analysis of secondary outcomes, high levels of non-adherence to ART and poor care engagement were evident at 6 months, with no differences between study arms. A trauma-focused, culturally-adapted individual intervention delivered by a non-specialist in the HIV care setting is feasible and acceptable. Preliminary findings suggest ImpACT has potential to reduce PTSD symptoms and increase ART adherence motivation, but a more intensive intervention may be needed to improve and maintain care engagement among this population. Trial Registration: ClinicalTrials.gov NCT02223390.

Keywords South Africa · HIV · Sexual violence · Traumatic stress · Adherence

Introduction

Individuals living with HIV report disproportionately high levels of interpersonal trauma and have higher rates of post-traumatic stress disorder (PTSD) than the general population [1, 2]. The psychosocial and behavioral sequelae that result from traumatic experiences can significantly impact HIV care-seeking behaviors and clinical outcomes [3–6]. Despite this, the evidence base for trauma-focused interventions among HIV-infected individuals is limited [7, 8]. A comprehensive review [7] identified only two interventions that have empirical support for the treatment of trauma-related symptoms in this population [9, 10]: one of prolonged exposure therapy [11] and the other based on stress and coping [12] in combination with components of trauma-focused cognitive behavioral therapy. Both studies were evaluated in the United States, and neither intervention focused on nor examined HIV care engagement as an outcome [9, 10]. As the global community strives to meet the 90-90-90 target (including 90% on antiretroviral therapy and 90% virally suppressed), there is a need to develop and evaluate trauma-focused interventions that can support sustained HIV care

✉ Kathleen J. Sikkema
kathleen.sikkema@duke.edu

1 Duke Global Health Institute, Duke University, Durham, NC, USA

2 Department of Psychology and Neuroscience, Duke University, Durham, NC, USA

3 Department of Psychiatry and Mental Health, University of Cape Town, Cape Town, South Africa

4 Department of Psychology and Neuroscience, Duke University, 417 Chapel Drive, Box 90086, Durham, NC 27708-0086, USA

engagement among individuals with trauma histories in low- and middle-income countries (LMICs).

In South Africa, where HIV prevalence is particularly high [13], sexual trauma, including childhood and adult sexual abuse, is common in the general population and is likely elevated among women living with HIV [1, 14]. In a clinic-based screening of women in HIV care in South Africa, 51% reported a history of sexual abuse (23% during childhood/adolescence and 37% during adulthood) [15]. An HIV diagnosis and a history of sexual trauma can lead to compounded shame and stigma and impact HIV care engagement [16, 17]. This was evident in qualitative work in South Africa [18], where women with sexual trauma histories often experienced a delay of several years between HIV diagnosis and enrollment in HIV care. This delay was attributed to feelings of shame related to recent or ongoing sexual trauma experiences. In many cases, women attributed their HIV infection directly to their experiences of sexual abuse. Once engaged in HIV care, women continued to face barriers; several women noted how taking antiretroviral therapy (ART) brought up disturbing memories of the sexual trauma, and no women had disclosed their sexual trauma to an HIV care provider [18].

Traumatic stress symptoms, such as avoidance [19] and dissociation [20, 21] may persist for years after the occurrence of sexual trauma and impact women's capacity to fully engage in HIV care [22]. In addition, co-morbid mental health disorders, such as depression, anxiety disorder, and substance use may further interfere with care [23–25]. The impact of sexual trauma on HIV care engagement has implications for clinical outcomes [26–28], explaining in part why individuals with traumatic histories progress faster to AIDS and face more AIDS-related mortality [22, 29, 30].

Addressing the impact of sexual trauma on HIV care behaviors and outcomes requires a model of trauma-informed care, whereby trauma is recognized (typically through routine screening), targeted interventions are delivered, and referrals are made to specialized services [31, 32]. To date, no trauma-informed interventions to promote HIV care engagement in LMICs have been identified [33], although evaluation of an intervention for HIV-infected women with histories of gender-based violence is on-going in Kenya [34, 35]. A major issue in trauma-informed care models in LMICs is the availability of specialized personnel to deliver interventions, and the resources and time available for supplemental interventions. This necessitates that interventions should be designed for delivery by non-specialized health care providers or lay providers, an approach known as task-shifting or task-sharing [36, 37], and that they should be easily integrated into the existing care delivery structure. To address the unique needs of HIV-infected women who have a history of sexual trauma, it is necessary to develop brief and scalable approaches to address the accumulated impacts of trauma, in order to help them develop strategies for long-term HIV care engagement.

The goal of this study was to conduct a pilot clinical trial of a newly developed 7-session psychological intervention (four individual sessions and three group sessions) for HIV-infected women with sexual abuse histories, in a low-resource, primary care setting to (1) determine the feasibility and acceptability of the intervention, (2) explore the potential efficacy of the intervention on mental health (primary outcomes) and HIV care engagement (secondary outcomes) as ART is initiated, and (3) assess the feasibility of conducting a full scale randomized controlled trial.

Methods

Participants and Setting

HIV-infected women newly initiating ART were recruited between March 2016 and January 2017 from a primary health care clinic in a peri-urban township of Cape Town, South Africa, serving an impoverished and densely populated area. Community resources and local infrastructure are limited, and socioeconomic indicators point to high rates of poverty and hardship. One-third of residents completed Grade 12 education, 38% were unemployed, 78% reported an annual household income below 3200 South African rand (approx US $225), and 56% live in informal dwellings [38]. The clinic is one of the public service HIV treatment centers where patients receive free HIV care, including ART. At the time of the study, the clinic had a total patient load of over 2500 adult HIV patients. ART initiation at the clinic follows a standard protocol as per South African government guidelines [39]. After receiving an HIV diagnosis, patients are clinically assessed based on current ART initiation criteria (i.e., CD4 $\leq$ 500 cells/mm^3, AIDS defining illness). Patients who do not yet meet ART initiation criteria receive care and regular assessments (e.g., CD4 count monitoring) in the Wellness sub-clinic until they meet the ART initiation criteria. Patients who meet ART initiation criteria typically receive three sessions of adherence "readiness" counseling, after which they are to initiate ART.

Women were eligible to participate in the study if they met the following criteria: (1) HIV-infected and meeting ART initiation criteria; (2) history of sexual abuse, defined as sexual abuse or assault that occurred during childhood, adolescence or adulthood, based on the WHO CIDI [40] and the Childhood Trauma Questionnaire [41]; (3) 18 years or older; (4) Xhosa speaking; and (5) accessing HIV care services at the study clinic. Suicidal ideation and severity were assessed using items adapted from the suicidality subscale of the Mini International Neuropsychiatric Interview [42]. Women with current suicidal intent

were excluded and referred for psychiatric treatment. Suicidal risk was assessed throughout the study, and referrals provided as needed. A target sample size of 60 was chosen as adequate to examine the feasibility and acceptability of a pilot RCT with two conditions [43]. Reporting of study methods and results followed the CONSORT 2010 statement, as extend to pilot randomized controlled trials [44].

Procedures

All women who were eligible for ART initiation were referred to the study by the Wellness sub-clinic staff. Study staff consented and screened patients for eligibility based on reported sexual abuse history. Potential participants were informed of the study focus on sexual trauma following completion of the screening.

Patients who met eligibility criteria and gave written informed consent to the trial were scheduled to complete the baseline assessment (typically within 1–5 days following screening), prior to receiving the standard adherence counseling sessions. Participants were randomly assigned (1:1) to the standard of care control condition (SoC: 3 adherence "readiness" sessions) or the experimental intervention condition (SoC, plus ImpACT) using a small block (size 8 or 10) randomization procedure. Condition assignments were placed in sealed envelopes, blinded to study staff until assignment. Due to the nature of the intervention conditions, neither participants nor staff could be blinded to condition assignment. All participants completed follow-up assessments at 3-months and 6-months after baseline to comprise a 6-month study period. Interviewer-administered assessments were conducted within a private room in the clinic and lasted approximately 90 min. Participants were remunerated R100 (approx. $8) for each assessment and R50 (approx. $4) for each ImpACT intervention session. All study procedures were approved by the institutional review boards at both participating institutions. The trial was registered at ClinicalTrials.gov (NCT02223390).

Figure 1 displays the CONSORT flow diagram of participant progress through the phases of the study. Of the 138 who completed screening, 79 (57.2%) met eligibility criteria for the study. Of the eligible patients, 64 (81.0%) were enrolled and completed the baseline assessment. Retention in the 3- and/or 6-month assessment was 85.9% and no significant differences by study condition in the percentage of participants lost to follow-up were observed. Participants lost to follow-up at the 6-month assessment were significantly more likely than those retained to have reported hazardous drinking (69.2% vs. 37.3%, $p = 0.04$) and recent physical intimate partner violence at baseline (46.2% vs. 17.65%, $p = 0.03$).

Study Conditions

ImpACT Intervention

The development of ImpACT was guided by an evidence-based, trauma-focused stress and coping intervention among HIV-infected adults [10, 45, 46], and culturally adapted using extensive formative research [18]. The intervention was designed to reduce traumatic stress and improve HIV care engagement by developing effective strategies for coping with HIV and trauma, and enhancing adherence to ART, but was not singularly intended as a treatment for PTSD. The time of ART initiation was viewed as a 'window of opportunity' to improve HIV care engagement and set the stage for sustained adherence to ART. ImpACT was developed for integration in a primary care clinic in a low resource setting. As such, the intervention was brief, focused, and delivered by a lay provider (non-specialist in mental health). The provider was trained by the study PI and coordinator to facilitate ImpACT using an intervention manual, participant workbook and culturally tailored visual aids, and received ongoing supervision from a South African clinical psychologist. Individual supervision was conducted on a weekly basis and included review of clinical notes, workbook content and reflection on intervention process.

The ImpACT intervention consisted of four individual sessions (60 min, on average) and three group sessions (90 min). Individual sessions typically began within 1 week of completing the standard adherence counseling (SoC, see below) and occurred weekly, as ART was being initiated. The first session ("Understanding the Combined Stress of Sexual Trauma and HIV") addressed the commonalities of stressors in trauma and HIV, and provided an opportunity for the participant to discuss her experiences and related feelings. A values exercise was developed, based on our formative research, to identify personal motivations for HIV care engagement, and a "Start Strong, Stay Strong" visual theme was used to focus on long-term adherence to ART. The "3H (Head, Heart, and Hands) Model" was developed and utilized to articulate the influence of trauma and HIV on thoughts ("Head"), feelings ("Heart") and relationships ("Hands"). The impact of sexual trauma on safety, trust, power and self-esteem (based on cognitive processing therapy) was adapted via a visual depiction of an *Imbiza* pot, a culturally relevant community-oriented item that represented these constructs and provided linkages between trauma and HIV. The second session ("Coping that Works") was focused on how to develop adaptive strategies. The "Coping Pebbles" exercise was developed to reflect the stress and coping model [12] and adapted to emphasize the emotional and physical burden of stress carried in daily life, and to discuss stress specific to trauma and HIV. A bag of small painted rocks represented changeable and unchangeable stressors;

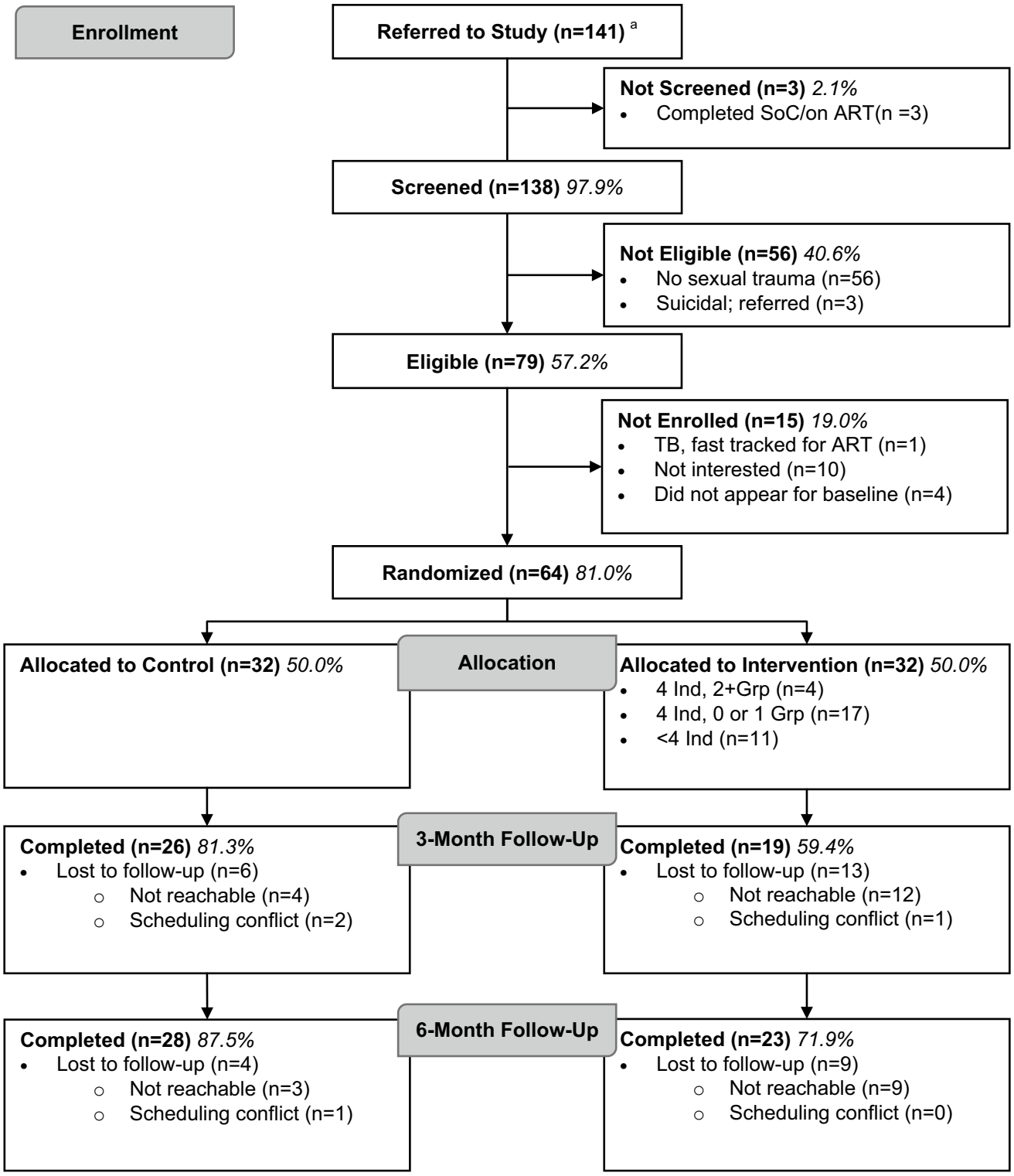

Fig. 1 CONSORT Flow Diagram of the study participants through the trial. [a] Of the 141 participants referred to the study, eight were reinitiating ART after defaulting treatment. Four did not meet eligibility criteria (no sexual trauma) and one did not appear for baseline. Three re-initiators were enrolled in the trial (two randomized to ImpACT and one to SoC)

the participant selected specific stressors, and based on stress appraisal, worked to develop problem- and emotion-focused coping strategies that would reduce avoidance and be effective for coping with trauma and engaging in HIV care. Effective strategies included acceptance and disclosure of HIV status, communication with health care providers, cognitive reframing of the traumatic consequences of HIV diagnosis, reduction of alcohol use, addressing family conflict, and managing emotional and behavioral responses to abusive partners, including conflicts related to HIV testing and disclosure. The third session ("Coping and HIV Care") built on all concepts from sessions 1 and 2 to identify behaviors and goals for successful engagement in HIV care and to address potential challenges and barriers that may interfere with ART adherence. Session 4 ("Impact of Sexual Trauma on Relationships and Next Steps") was a review of key constructs and activities, notably practice of adaptive coping strategies, with a focus on relationships and social interactions. Continued progress was reinforced, and engaging in HIV care in light of one's values (e.g., children, family, and community) was used to frame adherence and self-care, including as a form of empowerment.

Three subsequent group sessions were focused on consolidating concepts from ImpACT individual sessions, with opportunities for sharing challenges and successes, seeking social support, and generating coping strategies with peer input to refine strategies for adherence to ART and coping with HIV. The group sessions were co-facilitated by the ImpACT lay provider and a community care worker from the study clinic. The ImpACT intervention manual [47] is available upon request.

Fidelity to ImpACT Intervention Protocol After each session, detailed quality assurance worksheets were completed to document fidelity to intervention content, skills, and activities. Participant workbooks with session-by-session activities were completed with detailed notes on session content and process. The quality assurance data was reviewed frequently by the study coordinator, who held supervisory meetings on a regular basis.

Standard of Care (SoC) Adherence Counseling

SoC control condition participants received three sessions of adherence counseling, as required for patients prior to initiating ART in public HIV clinics in South Africa [39]. The sessions were delivered by a clinic counselor and included education about HIV and ART, the importance of full engagement in HIV care, and strategies for HIV disclosure. The sessions typically began a week after the Wellness Clinic visit when patients were informed of ART eligibility, and occurred weekly. After completing these three sessions, patients then advanced to initiate ART, approximately 1 month after study baseline. ImpACT participants also received the SoC adherence counseling sessions prior to beginning the ImpACT intervention.

Feasibility and Acceptability

Study feasibility was determined by patient willingness to be screened, proportion of women meeting trauma criteria, and flow of participants through the study. Feasibility of assessments was examined through self-report and medical record abstraction. The acceptability of the study was evaluated using a 5-item scale included in the 6-month assessment, which asked about the participant's general experience with the study, including their satisfaction with the amount of confidentiality and respect received, and their likelihood of recommending the study to other women (1 = strongly disagree to 4 = strongly agree; Cronbach's alpha = 0.87).

Intervention feasibility was monitored through session attendance and quality assurance data collection on intervention fidelity and supervision. The acceptability of the intervention was evaluated using three measures of participant feedback at 3- and 6-month assessments: (1) satisfaction with intervention, facilitator, frequency and length of sessions, ability of intervention to address specific issues, and overall ratings (1 = strongly disagree to 4 = strongly agree; Cronbach's alpha = 0.79); (2) ratings of usefulness of each of seven intervention components within the individual sessions (1 = not at all useful to 5 = extremely useful) (Cronbach's alpha = 0.77); and (3) open ended questions on logistical challenges, manner in which sexual trauma was addressed, and ways in which intervention impacted adherence to HIV care.

Measures

Measures were selected based on prior use in South Africa, and were translated into Xhosa and back-translated into English. Formative research and cognitive interviews were conducted on measures of traumatic stress and coping in order to ensure respect for context, comprehensible literacy levels, and cultural salience.

Demographics, Alcohol Use, and HIV-Related Health Characteristics

Demographics included questions about the participant's age, education, employment status, and relationship status. Hazardous drinking was assessed with the AUDIT-C, a three-question measure that evaluates frequency of drinking, quantity of drinks consumed on a typical day, and frequency of binge drinking [48]. HIV related questions (date of diagnosis, CD4 count, attendance of readiness sessions, date of ART initiation, ARV prescription information, and HIV

disclosure) were assessed through self-report and abstraction of medical record data.

Sexual Abuse, Intimate Partner Violence, and Exposure to Other Traumatic Events

Recent sexual abuse (in addition to sexual abuse during childhood, adolescence, and adulthood, per inclusion criteria), defined as sexual abuse or assault that occurred within the past 3 months, was assessed using three items based on the WHO Composite International Diagnostic Interview (CIDI) [40] (e.g., "As an adult, did anyone ever touch you in a sexual way or make you touch them in a sexual way against your will, when you made it clear through words or actions that you did not want to? If yes, has it happened in the last 3 months?"). Disclosure of sexual abuse or sexual violence to others, including family members, current partner (excluding the abuse partner), and healthcare providers was assessed using an adapted HIV disclosure instrument [49]. Physical intimate partner violence (physical IPV) occurring in adolescence, adulthood, and within the past 3 months was measured using three items from the physical IPV subscale of the revised Conflict Tactics Scale (CTS2) [50] (e.g., "Has a partner ever beat, kicked or hit you?"). Exposure to other traumatic events in adulthood and ever was measured using five traumatic events listed in the PTSD module of the WHO CIDI (e.g., "Have you ever been mugged, held up, car-jacked or threatened with a weapon?"; "Has someone very close to you died unexpectedly; for example, they were killed in an accident, murdered, or your son or daughter died?") [40].

Post-Traumatic Stress Disorder (PTSD)

PCL-5 [51], a 20-item self-report questionnaire, assessed severity of symptoms that parallel DSM-5 diagnostic criteria for PTSD. Participants were asked to indicate the extent to which they were bothered by problems experienced in the past month in relation to a traumatic experience of abuse or act of violence (0 = not at all to 4 = extremely). Total severity score (Cronbach's alpha = 0.94) and subscale totals (re-experiencing symptom category B; avoidance category C; negative alterations in cognitions and mood category D; and hyperarousal category E; Cronbach's alpha = 0.88, 0.83, 0.83, and 0.83, respectively) were examined at each of the three assessment points.

Coping

Coping was assessed using 43 items that were previously used to measure coping in Sub-Saharan Africa or among HIV-infected individuals [10, 52–57], in addition to 4 new items that were chosen based on cognitive interviewing and formative findings. Participants were asked how often they used these strategies in the past month to help deal with their HIV illness (1 = not at all to 4 = most of the time). A principal axis factor analysis with direct oblimin rotation was performed on the baseline data to explore the structure of coping items. Five items did not logically group with any factor and were removed from further analysis. In total, three factors were identified, which included active coping (13 items, e.g., "I made a plan and have taken steps to improve the situation"; Cronbach's alpha = 0.83), avoidant coping (16 items, e.g., "I bottled by feelings inside"; Cronbach's alpha = 0.79), and social/spiritual coping (13 items, e.g., "I talked with others with problems like mine"; Cronbach's alpha = 0.78).

Adherence Motivation

Motivation to take ART was measured using an adapted subscale of the LifeWindows Information-Motivation-Behavioral Skills ART Adherence Questionnaire (LW-IMB-AAQ) [58]. The LW-IMB-AAQ was developed to identify barriers to ART adherence among HIV-infected patients. The personal motivation subscale measures attitudes and beliefs about the impact of ART medication and the daily burden of ART adherence. For the present study, five items were included based on their relevance to South African women in a clinic setting, and a new item was added to measure the perceived difficulty of being able to take HIV medications with food as prescribed. The final scale included six questions with responses ranging from 1 = strongly disagree to 5 = strongly agree (Cronbach's alpha = 0.76). All six questions were reverse-scored and summed to obtain a total score with a possible range of 6–30, with larger values indicating greater motivation to take ART.

HIV Care Engagement

HIV care engagement was measured using self-reported ART adherence and medical record abstraction. Any self-reported non-adherence was evaluated by asking the participant how many days she missed taking her medication within the past month [59]. Using the abstracted medical record data, retention in care was measured by computing days between consecutive kept HIV-related visits and assessing whether 60 days or more elapsed between any two visits or between the participant's last kept visit and the end of the study window [60]. Additionally, the viral load data abstracted from medical records was dichotomized as suppressed (< 1000 copies/ml) or not suppressed (≥ 1000 copies/ml) [61]. Data was abstracted for the first assessment of viral load, typically 3–4 months post ART initiation, and thus the test result most approximate to the 6-month assessment.

Exploratory Data Analysis to Evaluate Potential Intervention Efficacy

Study data were double-entered using REDCap, a secure, web-based application hosted at Duke University [62]. Descriptive statistics were used to characterize the sample at baseline, with *t* tests and χ^2 tests examining between-group differences for continuous and categorical variables, respectively. The conditions were compared based on demographic factors, abuse histories, and HIV history.

Although exploratory in approach, our primary hypotheses examined the short term effects of ImpACT on mental health outcomes. To assess the changes in PTSD symptoms, coping, and adherence motivation by intervention condition, linear mixed models were fit using the PROC MIXED procedure in SAS software version 9.4 (SAS Institute, Inc., Cary, NC). To explore differences between conditions in clinically significant change of PTSD symptoms, χ^2 tests compared proportions of participants with a > 20 point reduction in the total severity score from baseline to 3-month and baseline to 6-month assessments [63]. Participants were retained in these analyses regardless of intervention exposure, following an intent-to-treat analysis of the outcomes.

For our secondary outcomes, analysis of self-reported adherence excluded participants who did not initiate ART (n = 4 in ImpACT and n = 3 in SoC), and care engagement measures excluded both participants who did not initiate ART and those who officially transferred care to another clinic (n = 2 in ImpACT and n = 2 in SoC). To explore differences in adherence and care engagement, χ^2 tests compared proportions between conditions at 3-month and 6-month.

Results

Sample Characteristics

Characteristics of the study sample are described in Table 1. The average age of participants was 29.1 years (SD = 7.5) and most participants (78.1%) had not completed high school. While a quarter of participants reported current employment and a few reported occasional work, the majority of participants (68.7%) were unemployed. More than half (59.4%) were in relationship but not living with their partner, 15.6% were living with a partner, and 12.5% were married. Four participants were single (6.3%) and four were separated or divorced (6.3%) at baseline.

High rates of sexual abuse were reported across the life course, with 18.8% of participants reporting sexual abuse in childhood, nearly half (48.4%) reporting sexual abuse in adolescence, and over three-quarters (76.6%) reporting sexual abuse in adulthood. Moreover, 40.6% of participants reported experiencing sexual abuse within the last 3 months at baseline. While more than half of participants (54.7%) had disclosed at least one sexual abuse experience to a family member, only 9.4% had ever told a health care provider about their history of sexual abuse. Prevalence of lifetime physical intimate partner violence was also high (84.4%), with 23.4% of the sample experiencing physical IPV within the last 3 months at baseline. Nearly the entire sample (92.2%) reported exposure to other traumatic events, with 87.5% reporting exposure in adulthood.

Most of the study participants were recently diagnosed with HIV, with 53.1% diagnosed within the last 1 month and 57.8% diagnosed within the last 3 months of enrolling in the study. The overall proportion of women who had disclosed their HIV status was high, with 92.2% of participants having told somebody about their diagnosis. However, 25.0% of participants with a current partner reported not having disclosed their HIV status to this partner. The average CD4 count of study participants at the time of ART initiation was 317.9 cells/μl. Based on medical record review, 87.5% of SoC participants and 90.6% of ImpACT participants completed the three adherence counseling sessions required for ART initiation. Overall, 10.9% of participants did not initiate ART during the study period. Of the participants who initiated ART, 94.6% were on a fixed dose combination (FDC) with tenofovir (TDF), emtricitabine (FTC) and efavirenz (EFV).

No significant differences for any of these sample characteristics were observed between treatment conditions.

Intervention Trial Feasibility and Acceptability

Fidelity to the ImpACT intervention protocol for individual sessions was high. An independent coder estimated level of fidelity to the ImpACT intervention for the individual sessions, with 97.8% coverage specific to each session's protocol. Due to challenges in group session attendance, limited quality assurance data for group sessions were available, although for the group sessions that were implemented, intervention fidelity was also high. Overall, the mean number of individual sessions attended was 3.1 (SD = 1.3; range 0–4), with 65.6% of participants attending all four sessions. Three participants (9.4%) attended only one session and only one attended no sessions. For group sessions, attendance was poor, with only 25.0% receiving any group session*s*. Twenty-five percent of enrolled participants were referred for psychological or psychiatric services over the course of the study and no significant differences by study condition in the portion of participants receiving referrals were observed.

The mean score for overall study acceptability (range 1–4) was 3.79 at 3 months and 3.78 at 6 months, representing high levels of study acceptability among participants in both study arms. Among intervention participants, the mean

Table 1 Study sample characteristics

	Study Condition		
	SoC (n = 32) n (%)	ImpACT (n = 32) n (%)	Total sample (n = 64) n (%)
Demographic characteristics			
Age, mean (SD)	29.0 (8.4)	29.2 (6.6)	29.1 (7.5)
Education			
Some high school or less	24 (75.0)	26 (81.3)	50 (78.1)
Completed high school	5 (15.6)	5 (15.6)	10 (15.6)
Some university or more	3 (9.4)	1 (3.1)	4 (6.3)
Current employment status			
Currently working	6 (18.7)	10 (31.2)	16 (25.0)
Casual/sometimes working	2 (6.3)	2 (6.3)	4 (6.3)
Not working	24 (75.0)	20 (62.5)	44 (68.7)
Relationship status			
Single	2 (6.3)	2 (6.3)	4 (6.3)
In a relationship, not living together	17 (53.1)	21 (65.6)	38 (59.4)
In a relationship, living together	5 (15.6)	5 (15.6)	10 (15.6)
Married	4 (12.5)	4 (12.5)	8 (12.5)
Separated/divorced	4 (12.5)	0 (0)	4 (6.3)
Sexual abuse history			
Sexual abuse in childhood	6 (18.8)	6 (18.8)	12 (18.8)
Sexual abuse in adolescence	17 (53.1)	14 (43.8)	31 (48.4)
Sexual abuse in adulthood	25 (78.1)	24 (75.0)	49 (76.6)
Recent (last 3 months) sexual abuse	12 (37.5)	14 (43.8)	26 (40.6)
Physical intimate partner violence			
Ever experienced physical IPV	24 (75.0)	30 (93.8)	54 (84.4)
Recent (last 3 months) physical IPV	6 (18.8)	9 (28.1)	15 (23.4)
Other traumatic events			
Lifetime exposure to traumatic event	28 (87.5)	31 (96.9)	59 (92.2)
Adulthood exposure to traumatic event	27 (84.4)	29 (90.6)	56 (87.5)
Hazardous drinking	13 (40.6)	15 (46.9)	28 (43.8)
HIV-related characteristics			
Recent HIV diagnosis (< 3 months)	19 (59.4)	18 (56.3)	37 (57.8)
CD4 count (mean, SD)	286.9 (115.6)	348.8 (163.5)	317.9 (143.9)
Initiated ART during study period	28 (87.5)	29 (90.6)	57 (89.1)

No significant differences were found between the two conditions

score for acceptability of the intervention (range 1–4) was 3.77 at 3-month and 3.71, also representing high levels of acceptability of the intervention. Ratings of the usefulness of each of seven intervention components within the individual sessions (range 1–5) were also high, with mean scores of 4.84 at 3-month and 4.91 at 6-month.

Longitudinal Effects on Traumatic Stress Outcomes, Coping, and Motivation to Adhere

Means and results for overall effect of condition by time for the primary psychological outcomes are reported in Table 2. Mixed model parameter estimates of time effects from baseline to 3-month (post individual sessions) as well as baseline to 6-month revealed significant decreases in overall PTSD symptom severity scores and all PTSD subscales across both study conditions. The time by condition interaction parameter estimates revealed significantly greater reductions in the ImpACT arm compared to the SoC for avoidance symptoms of PTSD (Cluster C; $F_{(1,43)} = 5.05$, $p = 0.03$) as well as hyperarousal symptoms of PTSD (Cluster E; $F_{(1,43)} = 6.78$, $p = 0.01$) from baseline to 3-month. The time by condition interaction parameter estimate suggested a trend for greater reductions in overall PTSD symptom severity scores in the ImpACT arm compared to SoC from baseline to 3-month as well ($F_{(1,43)} = 3.15$, $p = 0.08$). In mixed models of time effects from baseline to 6-month, the time by condition interaction parameter estimates did

Table 2 Intervention effects on traumatic stress, coping, and motivation to adhere to ART

	Baseline (n = 64)	3-month follow-up (n = 45)	Baseline to 3-month overall effect	6-month follow-up (n = 51)	Baseline to 6-month overall effect
	Mean (SE)	Mean (SE)	F values: Time / Condition × Time	Mean (SE)	F values: Time / Condition × Time
PCL—total symptom severity score					
ImpACT	43.28 (3.88)*	25.79 (5.40)	15.84** / 3.15†	28.61 (5.04)	7.54** / 0.90
SoC	30.72 (3.58)	23.04 (3.60)		22.50 (3.47)	
PCL—Cluster B					
ImpACT	10.03 (1.20)	6.42 (1.52)	10.58** / 1.15	7.30 (1.30)	4.42* / 0.22
SoC	7.72 (1.12)	5.27 (1.26)		5.82 (1.02)	
PCL—Cluster C					
ImpACT	4.53 (0.52)*	2.21 (0.63)	17.67** / 5.05*	2.96 (0.60)	5.09** / 1.37
SoC	3.03 (0.46)	2.23 (0.39)		2.71 (0.47)	
PCL—Cluster D					
ImpACT	15.84 (1.45)*	9.68 (2.31)	12.63** / 0.58	10.43 (1.93)	8.19** / 0.21
SoC	11.66 (1.37)	7.54 (1.34)		7.21 (1.43)	
PCL—Cluster E					
ImpACT	12.88 (1.28)**	7.47 (1.36)	8.01** / 6.78*	7.91 (1.54)	5.32** / 2.55†
SoC	8.31 (1.13)	8.00 (1.21)		6.75 (1.10)	
Avoidant coping					
ImpACT	2.45 (0.11)	2.10 (0.12)	14.24** / 0.15	2.17 (0.13)	12.42** / 0.69
SoC	2.40 (0.08)	2.13 (0.07)		1.99 (0.09)	
Spiritual/social coping					
ImpACT	2.54 (0.10)	2.89 (0.11)	3.93† / 2.58	2.90 (0.10)*	2.47† / 2.95†
SoC	2.62 (0.11)	2.66 (0.11)		2.58 (0.10)	
Motivation to adhere					
ImpACT	19.00 (1.27)	23.84 (1.46)	11.24** / 4.27*	21.63 (1.60)	5.74** / 2.40†
SoC	20.88 (1.13)	22.40 (1.27)		21.33 (1.19)	

Between-group differences within each time point denoted at $^{\dagger}p < 0.10$, $*p < 0.05$, and $**p < 0.01$, respectively

not reach statistical significance, though results suggested a trend for greater reductions in hyperarousal symptoms of PTSD in the ImpACT arm compared to the SoC (Cluster E; $F_{(2,93)} = 2.55$, $p = 0.08$).

Exploratory post hoc analysis revealed that a significantly larger proportion of participants in the ImpACT arm compared to SoC had clinically significant reductions in total symptom severity scores from baseline to 3-month assessments (47.4% vs. 15.4%; $p = 0.02$). While this trend continued into the 6-month assessment (39.1% vs. 25.0%), the difference did not reach statistical significance.

Mixed model parameter estimates of time effects from baseline to 3-month as well as baseline to 6-month revealed significant decreases in levels of avoidant coping as well as significant increases in levels of social/spiritual coping and adherence motivation across both study arms (Table 2). Changes in the levels of active coping over time did not reach statistical significance. The time by condition interaction parameter estimate for social/spiritual coping revealed marginally larger increases within the ImpACT arm compared to the SoC from baseline to 6-month ($F_{(2,89)} = 2.95$, $p = 0.06$).

Additionally, significant time by condition interaction parameter estimates were observed for adherence motivation, suggesting participants in the ImpACT arm reported greater increases in their motivation to adhere to ART than those in the SoC arm from baseline to 3-month ($F_{(1,42)} = 4.27$, $p = 0.05$), with a potential trend observed from baseline to 6-month ($F_{(2,89)} = 2.40$, $p = 0.10$).

Exploration of Longitudinal Effect on Adherence and Care Engagement

Among ART initiators, high rates of non-adherence to treatment (missed medication past month) were reported in both conditions at 3-month (44.0% vs. 36.8% in ImpACT vs. SoC; χ^2 (1) = 0.23, $p = 0.63$) and 6-month (42.3% vs. 36.4% in ImpACT vs. SoC; χ^2 (1) = 0.18, $p = 0.67$). Medical record data also suggested high levels of non-retention in care, with 42.3% of ImpACT participants and 33.3% of SoC participants having a 60 day or greater gap between any two consecutive appointments, or between their last appointment and the end of their 6-month study window (χ^2 (1) = 0.45, $p = 0.50$). Viral load data from the abstracted medical records, representing 3–4 months post ART initiation, revealed that among individuals who had viral load data, 15.8% of ImpACT participants and 20.0% of SoC participants had an unsuppressed viral load (i.e., ≥ 1000 copies/ml; χ^2 (1) = 0.13, $p = 0.72$). However, if participants who did not initiate ART and those with poor care engagement who were therefore missing viral load data are assumed to have unsuppressed viral loads, and participants who officially transferred to another clinic are assumed to have a suppressed viral load, the overall proportion of study participants with unsuppressed viral loads reaches 39.1%, suggesting low levels of viral suppression overall. Exploratory analysis revealed no differences on secondary outcomes of adherence and care engagement between study arms.

Discussion

HIV-infected South African women initiating ART in a low-resource, public clinic reported high levels of sexual abuse, interpersonal trauma, and traumatic stress. A significant proportion of these women were newly HIV diagnosed, with experiences of sexual violence ongoing for many, indicative of the syndemic nature of HIV and trauma in this setting. In this study, we conducted an exploratory clinical trial of a culturally-adapted, task-shifted coping intervention, developed through formative research and based on a theoretically grounded, evidence-based intervention addressing HIV and trauma [10]. ART initiation was conceptualized as a window of opportunity to address the emotional and behavioral consequences of sexual trauma, and potentially impact HIV care engagement. The study demonstrated the feasibility of conducting a clinical trial, and the feasibility and acceptability of the individual intervention sessions, delivered with high rates of fidelity by a lay provider in mental health.

ImpACT, a brief coping intervention for HIV-infected women with a history of sexual abuse, was shown to reduce traumatic stress and increase motivation to adhere to treatment as ART was initiated. This preliminary effect was evident post intervention (3 months from baseline), with trends suggesting a potential impact at 6-month follow-up. Overall, all participants reported a reduction in PTSD symptoms, with ImpACT participants reporting a greater reduction in avoidance and arousal symptoms, with a trend for total symptom severity reduction. In further support of ImpACT's potential to reduce PTSD, an exploratory analysis demonstrated that significantly more ImpACT participants reported a clinically significant reduction in overall PTSD symptoms, with nearly half reporting a reduction of 20 points or more, moving most of those participants below the diagnostic threshold for PTSD. A similar pattern of results indicated increased motivation among ImpACT participants to adhere to ART post-intervention, with a trend suggesting a continued effect at the 6-month follow-up assessment. Lastly, while avoidant coping decreased among all study participants, ImpACT participants demonstrated an increased level of social/spiritual coping at the 6-month follow assessment.

Taken together, these preliminary results suggest the potential for a brief coping intervention for HIV-infected women with extensive and ongoing traumatic experiences to reduce PTSD symptoms and improve motivation to adhere to HIV care. These preliminary effects are primarily evident post-intervention, with less clear support at the 6-month follow-up assessment. In addition, although the pilot study was not powered to evaluate psychological or clinical outcomes, levels of non-adherence across outcomes were similar between conditions at 6-month follow-up based on self-report and medical record abstraction of gaps between kept visits and viral load suppression. The overall challenges of adherence and viral suppression, with nearly 40% of our sample not suppressed at first viral load, suggest high levels of poor care engagement, supporting the need for trauma-informed interventions in this context.

Notably, while the individual sessions were considered feasible and acceptable, based on high levels of satisfaction with the content and interventionist, implementation of the group sessions met significant challenges and barriers. Although the study was designed to explore the additional benefit of group sessions, the low rate of attendance permitted the follow-up period between the 3- and 6-month assessments to serve as a form of no-intervention, maintenance period. The effectiveness of group intervention has been documented in other similar settings [64], and despite the acceptability of group sessions in our formative research, group sessions were unsuccessful in this study likely due to concerns of stigma and privacy, and difficulties with scheduling and transportation. Thus, although the exploratory outcomes suggest the potential for individual ImpACT sessions to effect change in the short-term, an intervention of greater intensity and/or duration should be considered for this population in a full scale trial. This could include, for example,

greater number of individual sessions that would replace group sessions, along with booster sessions over time. This modification to ImpACT could provide opportunities for further coping skills development, utilizing practice and application to new stressors, including barriers to adherence and re-emergence of avoidance and PTSD symptoms. This may be particularly necessary to demonstrate long-term effects on care engagement among HIV-infected women experiencing high levels of traumatic stress, and potentially ongoing sexual and physical violence.

Even within this syndemic context [65, 66], the ImpACT intervention and conduct of the trial were considered feasible across a variety of indicators. In collaboration with clinic providers, we were able to systematically refer and screen women for traumatic experiences. Based on our formative research findings [18], many women had not previously disclosed their sexually traumatic experiences, and few to none had disclosed in the health care setting. The prevalence of sexual abuse, intimate partner violence, and PTSD in our screened sample was higher than many HIV-positive studies [1], strongly supporting the need for a trauma-focused intervention in the context of differentiated care whereby scarce resources are allocated to individuals who may be most vulnerable and in need of support [67]. Trial retention overall was similar to or better than prior adherence intervention studies in varied settings [68], with an impressive 80% retention at 6 months among women in this stressful context. Lastly, individual session intervention dosage among ImpACT participants was similar to other studies of trauma treatment [9, 10, 69].

Study Limitations

As a pilot feasibility study, there are limitations to the study design, primarily that the study was under-powered to evaluate effects, and the preliminary analysis should be considered exploratory and with the purpose of informing a large-scale trial. Although the preliminary findings support the potential for the ImpACT intervention to reduce traumatic stress and improve adherence motivation, all study participants improved over time on a number of psychological indicators. Possible explanations for the overall improvement over time include the following: (1) potential improvement in physical health due to ART initiation, with resulting decreases in psychological distress, (2) openly discussing experiences of sexual abuse and trauma in the context of the baseline study procedures, possibly for the first time, (3) supportive study staff, including repeated opportunities through assessments to acknowledge and report on various psychological symptoms and daily life stressors, (4) referrals for psychiatric and psychological services across study arms as needed, and (5) potential effect of adherence counseling sessions received as standard of care by all participants.

Although there were advantages of utilizing ART initiation as a window of opportunity for intervention, this timing also presented challenges and potential limitations in the study design. With the clinic-required adherence counseling sessions serving as the standard of care control condition, participants were typically screened, enrolled, completed baseline and randomized within days of learning they needed to initiate ART; for some, this was immediately after receiving an HIV diagnosis. This process potentially created a high level of stress for participants and could be one explanatory factor in the differential loss to follow-up among women experiencing intimate partner violence and those reporting hazardous drinking upon enrollment in the trial. In contrast, study screening provided an opportunity for suicidality assessment and psychiatric referral for a number of participants not likely available through standard clinic procedures. Future research must consider alternative control conditions and timing of study entry, such that outcomes can remain focused on preventing non-adherence and maintaining care engagement, while also broadening the time period for study enrollment.

When considering the generalizability of these findings, demographic characteristics should be considered. Another limitation was the absence of direct observation of sessions (for example, through audio recordings), to assess intervention fidelity. In addition, the accuracy of self-reported adherence and medical record review cannot be confirmed, and future research should utilize viral load testing within the study protocol and consider biomarkers of medication to measure adherence, such as dried blood spots or hair samples.

Conclusions

ImpACT, in an exploratory clinical trial, was shown to reduce traumatic stress and increase ART adherence motivation among HIV-infected women with sexual abuse histories. A brief coping intervention, developed and culturally adapted based on an evidence-based approach to HIV and trauma, and delivered by a non-specialist in a public primary care clinic in Cape Town, was found to be feasible and acceptable for individual sessions. Future research should evaluate the ImpACT intervention, with modifications based on lessons learned in this pilot trial, in a full-scale RCT to assess its long-term effects on traumatic stress, coping and HIV care engagement. With South Africa currently implementing test-and treat guidelines [70, 71], but with continuing drop off across the HIV care cascade [72, 73], trauma-informed interventions are needed in this syndemic context to increase and maintain uptake of and adherence to ARV treatment.

Acknowledgements This study was funded by a Grant from NIMH (R34 MH102001). We also acknowledge support received from the Duke Center for AIDS Research (P30 AI064518), and the Duke Interdisciplinary Research Training Program in AIDS (T32 AI007392). We gratefully acknowledge the participants who contributed time and energy to this study.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. (Duke C0147, UCT 071/2014).

Informed Consent Informed consent was obtained from all individual participants included in the study.

References

1. Seedat S. Interventions to improve psychological functioning and health outcomes of HIV-infected individuals with a history of trauma or PTSD. Curr HIV/AIDS Rep. 2012;9(4):344–50.
2. Machtinger E, Wilson T, Haberer J, Weiss D. Psychological trauma and PTSD in HIV-positive women: a meta-analysis. AIDS Behav. 2012;16(8):2091–100.
3. LeGrand S, Reif S, Sullivan K, Murray K, Barlow ML, Whetten K. A review of recent literature on trauma among individuals living with HIV. Curr HIV/AIDS Rep. 2015;12(4):397–405.
4. Whetten K, Shirey K, Pence BW, Yao J, Thielman N, Whetten R, et al. Trauma history and depression predict incomplete adherence to antiretroviral therapies in a low income country. PLoS ONE. 2013;8(10):e74771.
5. Aaron E, Criniti S, Bonacquisti A, Geller PA. Providing sensitive care for adult HIV-infected women with a history of childhood sexual abuse. J Assoc Nurses AIDS Care. 2013;24(4):355–67.
6. Hatcher AM, Smout EM, Turan JM, Christofides N, Stockl H. Intimate partner violence and engagement in HIV care and treatment among women: a systematic review and meta-analysis. Aids. 2015;29(16):2183–94.
7. Applebaum AJ, Bedoya CA, Hendriksen ES, Wilkinson JL, Safren SA, O'Cleirigh C. Future directions for interventions targeting PTSD in HIV-infected adults. J Assoc Nurses AIDS Care. 2015;26(2):127–38.
8. McLean CP, Fitzgerald H. Treating posttraumatic stress symptoms among people living with HIV: a critical review of intervention trials. Curr Psychiatry Rep. 2016;18(9):83.
9. Pacella ML, Armelie A, Boarts J, Wagner G, Jones T, Feeny N, et al. The impact of prolonged exposure on PTSD symptoms and associated psychopathology in people living with HIV: a randomized test of concept. AIDS Behav. 2012;16(5):1327–40.
10. Sikkema KJ, Ranby KW, Meade CS, Hansen NB, Wilson PA, Kochman A. Reductions in traumatic stress following a coping intervention were mediated by decreases in avoidant coping for people living with HIV/AIDS and childhood sexual abuse. J Consult Clin Psychol. 2013;81(2):274–83.
11. Nemeroff CB, Bremner JD, Foa EB, Mayberg HS, North CS, Stein MB. Posttraumatic stress disorder: a state-of-the-science review. J Psychiatr Res. 2006;40(1):1–21.
12. Folkman S, Chesney M, McKusick L, Ironson G, Johnson D, Coates T. Translating coping theory into an intervention. In: Eckenrode J, editor. The social context of coping. New York, NY: Plenum Press; 1991. p. 239–60.
13. UNAIDS. UNAIDS data 2017. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS; 2017
14. Jewkes R, Penn-Kekana L, Levin J, Ratsaka M, Schrieber M. Prevalence of emotional, physical and sexual abuse of women in three South African provinces. S Afr Med J. 2001;91(5):421–8.
15. Yemeke TT, Sikkema KJ, Watt MH, Ciya N, Robertson C, Joska JA. Screening for traumatic experiences and mental health distress among women in HIV care in Cape Town, South Africa. J Interpers Violence. 2017:0886260517718186.
16. Whetten K, Reif S, Whetten R, Murphy-McMillan LK. Trauma, mental health, distrust, and stigma among HIV-positive persons: implications for effective care. Psychosom Med. 2008;70(5):531–8.
17. Blashill AJ, Perry N, Safren SA. Mental health: a focus on stress, coping, and mental illness as it relates to treatment retention, adherence, and other health outcomes. Curr HIV/AIDS Rep. 2011;8(4):215–22.
18. Watt MH, Dennis AC, Choi KW, Ciya N, Joska JA, Robertson C, et al. Impact of sexual trauma on HIV care engagement: perspectives of female patients with trauma histories in Cape Town, South Africa. AIDS Behav. 2017;21(11):3209–18.
19. McIntosh R, Rosselli M. Stress and coping in women living with HIV: a meta-analytic review. AIDS Behav. 2012;16(8):2144–59.
20. Keuroghlian AS, Kamen CS, Neri E, Lee S, Liu R, Gore-Felton C. Trauma, dissociation, and antiretroviral adherence among persons living with HIV/AIDS. J Psychiatr Res. 2011;45(7):942–8.
21. Dallam S. Where does it hurt? How victimization impacts presentation and outcomes in primary care. In: Banyard VL, Edwards VJ, Kendall-Tackett K, editors. Trauma and physical health: understanding the effects of extreme stress and of psychological harm. London and New York: Routledge; 2009. p. 134–62.
22. Pence BW, Mugavero MJ, Carter TJ, Leserman J, Thielman NM, Raper JL, et al. Childhood trauma and health outcomes in HIV-infected patients: an exploration of causal pathways. J Acquir Immune Defic Syndr. 2012;59(4):409–16.
23. Brief DJ, Bollinger AR, Vielhauer MJ, Berger-Greenstein JA, Morgan EE, Brady SM, et al. Understanding the interface of HIV, trauma, post-traumatic stress disorder, and substance use and its implications for health outcomes. AIDS Care. 2004;16(Suppl 1):S97–120.
24. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry. 2005;62(6):593–602.
25. Seedat S, Stein DJ, Carey PD. Post-traumatic stress disorder in women: epidemiological and treatment issues. CNS Drugs. 2005;19(5):411–27.
26. Ironson G, O'Cleirigh C, Fletcher MA, Laurenceau JP, Balbin E, Klimas N, et al. Psychosocial factors predict CD4 and viral load change in men and women with human immunodeficiency virus in the era of highly active antiretroviral treatment. Psychosom Med. 2005;67(6):1013–21.
27. Reilly KH, Clark RA, Schmidt N, Benight CC, Kissinger P. The effect of post-traumatic stress disorder on HIV disease progression following hurricane Katrina. AIDS Care. 2009;21(10):1298–305.
28. Schafer KR, Brant J, Gupta S, Thorpe J, Winstead-Derlega C, Pinkerton R, et al. Intimate partner violence: a predictor of worse HIV outcomes and engagement in care. AIDS Patient Care STDS. 2012;26(6):356–65.
29. Leserman J, Pence B, Whetten K, Mugavero M, Thielman N, Swartz M, et al. Relation of lifetime trauma and

depressive symptoms to mortality in HIV. Am J Psychiatry. 2007;164(11):1707–13.
30. Campbell JC, Baty ML, Ghandour RM, Stockman JK, Francisco L, Wagman J. The intersection of intimate partner violence against women and HIV/AIDS: a review. Int J Injury Control Saf Promot. 2008;15(4):221–31.
31. Brezing C, Ferrara M, Freudenreich O. The syndemic illness of HIV and trauma: implications for a trauma-informed model of care. Psychosomatics. 2015;56(2):107–18.
32. Machtinger EL, Cuca YP, Khanna N, Rose CD, Kimberg LS. From treatment to healing: the promise of trauma-informed primary care. Womens Health Issues. 2015;25(3):193–7.
33. Sales JM, Swartzendruber A, Phillips AL. Trauma-informed HIV prevention and treatment. Curr HIV/AIDS Rep. 2016;13(6):374–82.
34. Onu C, Ongeri L, Bukusi E, Cohen CR, Neylan TC, Oyaro P, et al. Interpersonal psychotherapy for depression and posttraumatic stress disorder among HIV-positive women in Kisumu, Kenya: study protocol for a randomized controlled trial. Trials. 2016;17:64.
35. Opiyo E, Ongeri L, Rota G, Verdeli H, Neylan T, Meffert S. Collaborative interpersonal psychotherapy for HIV-positive women in Kenya: a case study from the mental health, hiv and domestic violence (MIND) study. J Clin Psychol. 2016;72(8):779–83.
36. Patel V. The future of psychiatry in low- and middle-income countries. Psychol Med. 2009;39(11):1759–62.
37. Petersen I, Lund C, Stein DJ. Optimizing mental health services in low-income and middle-income countries. Curr Opin Psychiatry. 2011;24(4):318–23. https://doi.org/10.1097/YCO.0b013e3283477afb.
38. Statistics South Africa. South African National Census of 2011. Pretoria, South Africa: Government of South Africa; 2011.
39. Department of Health. National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of hiv in children, adolsecents and adults. South Africa: Pretoria; 2015.
40. World Health Organization. Composite international diagnostic interview (CIDI), Version 1.0. Geneva: WHO; 1990.
41. Bernstein DP, Stein JA, Newcomb MD, Walker E, Pogge D, Ahluvalia T, et al. Development and validation of a brief screening version of the Childhood Trauma Questionnaire. Child Abuse Negl. 2003;27(2):169–90.
42. Lecrubier Y, Sheehan D, Weiller E, Amorim P, Bonora I, Harnett Sheehan K, et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to the CIDI. Eur Psychiatry. 1997;12(5):224–31.
43. Browne RH. On the use of a pilot sample for sample size determination. Stat Med. 1995;14(17):1933–40.
44. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ (Clinical research ed). 2016;355:i5239.
45. Sikkema KJ, Wilson PA, Hansen NB, Kochman A, Neufeld S, Ghebremichael MS, et al. Effects of a coping intervention on transmission risk behavior among people living with HIV/AIDS and a history of childhood sexual abuse. J Acquir Immune Defic Syndr. 2008;47(4):506–13.
46. Meade CS, Drabkin AS, Hansen NB, Wilson PA, Kochman A, Sikkema KJ. Reductions in alcohol and cocaine use following a group coping intervention for HIV-positive adults with childhood sexual abuse histories. Addiction. 2010;105(11):1942–51.
47. Sikkema KJ, Joska JA, Choi KW, Robertson C, Ciya N, Knettel BA, et al. ImpACT: improving AIDS care after trauma—intervention manual. Duke University and University of Cape Town; 2017.
48. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med. 1998;158(16):1789–95.
49. Kotze M, Visser M, Makin J, Sikkema K, Forsyth B. Psychosocial variables associated with coping of HIV-positive women diagnosed during pregnancy. AIDS Behav. 2013;17(2):498–507.
50. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised Conflict Tactics Scales (CTS2): development and preliminary psychometric data. J Fam Issues. 1996;17(3):283–316.
51. Blevins CA, Weathers FW, Davis MT, Witte TK, Domino JL. The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5): development and initial psychometric evaluation. J Trauma Stress. 2015;28(6):489–98.
52. Namir S, Wolcott DL, Fawzey FI, Alumbaugh MJ. Coping with AIDS: psychological and health implications. J Appl Soc Psychol. 1987;17(3):309–28.
53. Kotze M, Visser M, Makin J, Sikkema K, Forsyth B. The coping strategies used over a two-year period by HIV-positive women who had been diagnosed during pregnancy. AIDS Care. 2013;25(6):695–701.
54. Olley BO, Zeier MD, Seedat S, Stein DJ. Post-traumatic stress disorder among recently diagnosed patients with HIV/AIDS in South Africa. AIDS Care. 2005;17(5):550–7.
55. Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. Int J Behav Med. 1997;4(1):92–100.
56. Hansen NB, Harrison B, Fambro S, Bodnar S, Heckman TG, Sikkema KJ. The structure of coping among older adults living with HIV/AIDS and depressive symptoms. J Health Psychol. 2013;18(2):198–211.
57. Folkman S, Lazarus RS. Manual for the ways of coping questionnaire. Research ed. Palo Alto, CA: Consulting Psychological Press; 1988.
58. The LifeWindows Project Team. The LifeWindows Information Motivation Behavioral Skills ART Adherence Questionnaire (LW-IMB-AAQ). Center for Health, Intervention, and Prevention. University of Connecticut; 2006.
59. Chesney MA, Ickovics JR, Chambers DB, Gifford AL, Neidig J, Zwickl B, et al. Self-reported adherence to antiretroviral medications among participants in HIV clinical trials: the AACTG adherence instruments. Patient Care Committee & Adherence Working Group of the Outcomes Committee of the Adult AIDS Clinical Trials Group (AACTG). AIDS Care. 2000;12(3):255–66.
60. Mugavero MJ, Westfall AO, Zinski A, Davila J, Drainoni ML, Gardner LI, et al. Measuring retention in HIV care: the elusive gold standard. J Acquir Immune Defic Syndr. 2012;61(5):574–80.
61. World Health Organization. Consolidated guidelines on person-centred HIV patient monitoring and case surveillance. Geneva: WHO; 2017.
62. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377–81.
63. Weathers FW, Litz BT, Keane TM, Palmieri PA, Marx BP, Schnurr PP. The PTSD Checklist for *DSM-5* (PCL-5) 2013 (Scale available from the National Center for PTSD at www.ptsd.va.gov).
64. Bass JK, Annan J, McIvor Murray S, Kaysen D, Griffiths S, Cetinoglu T, et al. Controlled trial of psychotherapy for Congolese survivors of sexual violence. N Engl J Med. 2013;368(23):2182–91.
65. Singer M, Bulled N, Ostrach B, Mendenhall E. Syndemics and the biosocial conception of health. Lancet. 2017;389(10072):941–50.

66. Meyer JP, Springer SA, Altice FL. Substance abuse, violence, and HIV in women: a literature review of the syndemic. J Women's Health. 2011;20(7):991–1006.
67. Grimsrud A, Bygrave H, Doherty M, Ehrenkranz P, Ellman T, Ferris R, et al. Reimagining HIV service delivery: the role of differentiated care from prevention to suppression. J Int AIDS Soc. 2016;19(1):21484.
68. Rueda S, Park-Wyllie LY, Bayoumi A, Tynan A-M, Antoniou T, Rourke S, et al. Patient support and education for promoting adherence to highly active antiretroviral therapy for HIV/AIDS. Cochrane Database Syst Rev. 2006(3).
69. Hembree EA, Foa EB, Dorfan NM, Street GP, Kowalski J, Tu X. Do patients drop out prematurely from exposure therapy for PTSD? J Trauma Stress. 2003;16(6):555–62.
70. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: WHO; 2016.
71. Department of Health. Minister Aaron Motsoaledi: Health Dept Budget Vote 2016/17. 2016.
72. UNAIDS. Prevention Gap Report. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS; 2016.
73. Takuva S, Brown AE, Pillay Y, Delpech V, Puren AJ. The continuum of HIV care in South Africa: implications for achieving the second and third UNAIDS 90-90-90 targets. AIDS. 2017;31(4):545–52.